PD6 Exh 15

U.S. Department of Justice

United States Attorney
Southern District of New York

The Silvio J. Mollo Building
One Saint Andrew's Plaza
New York, New York 10007

April 22, 2019

Douglas B. Farquhar, Esq.
Hyman, Phelps & McNamara P.C.
700 13th Street, NW, Suite 1200
Washington, D.C. 20005

Re: Rochester Drug Co-operative – Deferred Prosecution Agreement

Dear Mr. Farquhar:

Pursuant to the understandings specified below, the Office of the United States Attorney for the Southern District of New York (the "Office") and the defendant Rochester Drug Co-operative, Inc. ("RDC"), under authority granted by its Board of Directors in the form of a Board Resolution (a copy of which is attached as Exhibit A), hereby enter into this Deferred Prosecution Agreement (the "Agreement").

The Criminal Information

1. RDC consents to the filing of a three-count Information (the "Information") in the United States District Court for the Southern District of New York (the "Court"), charging RDC with conspiracy to distribute controlled substances outside the scope of professional practice and not for a legitimate medical purpose, in violation of Title 21, United States Code, Section 846; conspiracy to defraud the United States, in violation of Title 18, United States Code, Section 371; and knowingly failing to furnish suspicious order reports to the United States Drug Enforcement Administration ("DEA"), in violation of Title 21, United States Code, Section 842(a)(5) and (c)(2), and Title 18, United States Code, Section 2. A copy of the Information is attached as Exhibit B. This Agreement shall take effect upon its execution by both parties (the "Effective Date").

Acceptance of Responsibility

2. RDC stipulates that the facts set forth in the Statement of Facts, attached hereto as Exhibit C and incorporated herein, are true and accurate, and admits, accepts and acknowledges that it is responsible under United States law for the acts of its officers and employees as set forth in the Statement of Facts. Should the Office pursue the prosecution that is deferred by this Agreement, RDC stipulates to the admissibility of the Statement of Facts in any proceeding including any trial and sentencing proceeding.

Payment and Forfeiture Obligation

3. As a result of the conduct described in the Information and the Statement of Facts, RDC agrees to pay $20,000,000 (the "Stipulated Forfeiture Amount") to the United States, pursuant to this Agreement.

4. RDC agrees that the Stipulated Forfeiture Amount represents a substitute *res* for moneys furnished to RDC in exchange for controlled substances in connection with RDC's conduct described in the Statement of Facts, and is subject to civil forfeiture to the United States pursuant to 21 U.S.C. § 881.

5. RDC further agrees that this Agreement, the Information and the Statement of Facts may be attached and incorporated into a civil forfeiture complaint (the "Civil Forfeiture Complaint") that will be filed against the Stipulated Forfeiture Amount. By this agreement, RDC expressly waives any challenge to that Civil Forfeiture Complaint and consents to the forfeiture of the Stipulated Forfeiture Amount to the United States. RDC agrees that it will not file a claim with the Court or otherwise contest the civil forfeiture of the Stipulated Forfeiture Amount and will not assist a third party in asserting any claim to the Stipulated Forfeiture Amount. RDC also waives all rights to service or notice of the Civil Forfeiture Complaint.

6. RDC shall transfer one half of the Stipulated Forfeiture Amount ($10,000,000) to the United States by no later than May 3, 2019 (or as otherwise directed by the Office following such date). Such payment shall be made by wire transfer to the United States Marshals Service, pursuant to wire instructions provided by the Office. The remaining half of the Stipulated Forfeiture Amount ($10,000,000) shall be paid over a five-year period at the rate of $2,000,000 per year in each subsequent year until 2024, with payment due on or before February 1st of each year. If RDC fails to timely make the payment required under this paragraph, interest (at the rate specified in Title 28, United States Code, Section 1961) shall accrue on the unpaid balance through the date of payment, unless the Office, in its sole discretion, chooses to reinstate prosecution pursuant to paragraphs 14 through 15 below. RDC certifies that the funds used to pay the Stipulated Forfeiture Amount are not the subject of any lien, security agreement, or other encumbrance. Transferring encumbered funds or failing to pass clean title to these funds in any way will be considered a breach of this Agreement.

7. RDC agrees that the Stipulated Forfeiture Amount shall be treated as a penalty paid to the United States government for all purposes, including all tax purposes. RDC agrees that it will not claim, assert, or apply for a tax deduction or tax credit with regard to any federal, state, local, or foreign tax for any portion of the $20,000,000 that RDC has agreed to pay to the United States pursuant to this Agreement.

Obligation to Cooperate

8. RDC agrees to cooperate fully with the Office, the DEA, and any other governmental agency designated by the Office regarding any matter relating to the conduct described in the Information or Statement of Facts, any investigation or prosecution of RDC's

current or former officers, agents, affiliates and employees, or any matter relating to unlawful conduct by RDC's current or former customers.

9. It is understood that RDC shall (a) truthfully and completely disclose all information with respect to the activities of RDC and its officers, agents, affiliates and employees concerning all matters about which the Office inquires of it, which information can be used for any purpose; (b) cooperate fully with the Office, DEA, any other law enforcement agency designated by the Office; (c) attend all meetings at which the Office requests its presence and use its best efforts to secure the attendance and truthful statements or testimony of any past or current officers, agents, or employees of RDC at any meeting or interview or before the grand jury or at trial or at any other court proceeding; (d) provide to the Office upon request any document, record, or other tangible evidence relating to matters about which the Office or any designated law enforcement agency inquires of it; (e) assemble, organize, and provide in a responsive and prompt fashion, and upon request, on an expedited schedule, all documents, records, information and other evidence in RDC's possession, custody or control as may be requested by the Office, DEA or designated law enforcement agency; (f) volunteer and provide to the Office any information and documents that come to RDC's attention that may be relevant to the Office's investigation of this matter, any issue related to the Statement of Facts, and any issue that would fall within the scope of the duties of the independent monitor (the "Independent Monitor") referred to in paragraph 29; (g) provide testimony or information necessary to identify or establish the original location, authenticity, or other basis for admission into evidence of documents or physical evidence in any criminal or other proceeding as requested by the Office, DEA or designated governmental agency, including but not limited to information and testimony concerning the conduct set forth in the Information and Statement of Facts; (h) bring to the Office's attention all criminal conduct by RDC or any of its agents or employees acting within the scope of their employment related to violations of the federal laws of the United States, as to which RDC's Board of Directors, senior management, or legal and compliance personnel are aware; (i) bring to the Office's attention any administrative, regulatory, civil or criminal proceeding or investigation of RDC or any agents or employees acting within the scope of their employment; and (j) commit no crimes whatsoever under the federal laws of the United States subsequent to the execution of this Agreement. Nothing in this paragraph shall require RDC to produce information protected by a valid claim of attorney-client privilege or the attorney work product doctrine.

10. RDC agrees that its obligations pursuant to this Agreement, which shall commence on the Effective Date, will continue for five years from the date of the Court's acceptance of this Agreement, unless otherwise extended pursuant to paragraphs 16 through 18 below. RDC's obligation to cooperate is not intended to apply in the event that a prosecution against RDC by this Office is pursued and not deferred.

Obligation to Report

11. It is understood that RDC shall promptly report to the DEA all suspicious orders as defined in the Controlled Substances Act and its implementing regulations, including but not limited to 21 C.F.R. § 1301.74. It is further understood that RDC shall promptly report to the DEA any of its customers that it knows or has reason to believe are distributing controlled substances outside the scope of professional practice and not for a legitimate medical purpose.

Deferral of Prosecution

12. In consideration of RDC's entry into this Agreement and its commitment to: (a) accept and acknowledge responsibility for its conduct, as described in the Statement of Facts, and acknowledge the filing of the Information; (b) cooperate with the Office, DEA, any other law enforcement agency designated by this Office; (c) make the payments specified in this Agreement; (d) comply with Federal criminal laws (as provided herein in paragraph 9); and (e) otherwise comply with all of the terms of this Agreement, the Office shall recommend to the Court that prosecution of RDC on the Information be deferred for five years from the date of the signing of this Agreement. RDC shall expressly waive indictment and all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution, Title 18, United States Code, Section 3161, Federal Rule of Criminal Procedure 48(b), and any applicable Local Rules of the United States District Court for the Southern District of New York for the period during which this Agreement is in effect.

13. It is understood that this Office cannot, and does not, agree not to prosecute RDC for criminal tax violations. However, if RDC fully complies with the terms of this Agreement, no testimony given or other information provided by RDC (or any other information directly or indirectly derived therefrom) will be used against RDC in any criminal tax prosecution. In addition, the Office agrees that, if RDC is in compliance with all of its obligations under this Agreement, the Office will, within thirty (30) days after the expiration of the period of deferral (including any extensions thereof), seek dismissal with prejudice as to RDC of the Information filed against RDC pursuant to this Agreement. Except in the event of a violation by RDC of any term of this Agreement or as otherwise provided in paragraph 14, the Office will bring no additional charges against RDC, except for criminal tax violations, relating to its conduct as described in the admitted Statement of Facts. This Agreement does not provide any protection against prosecution for any crimes except as set forth above and does not apply to any individual or entity other than RDC. RDC and the Office understand that the Agreement to defer prosecution of RDC can only operate as intended if the Court grants a waiver of the Speedy Trial Act pursuant to 18 U.S.C. § 3161(h)(2). Should the Court decline to do so, both the Office and RDC are released from any obligation imposed upon them by this Agreement, and this Agreement shall be null and void, except for the tolling provision set forth in paragraph 14.

14. It is further understood that should the Office in its sole discretion determine that RDC has: (a) knowingly given false, incomplete or misleading information either during the term of this Agreement or in connection with the Office's investigation of the conduct described in the Information and Statement of Facts, (b) committed any crime under the federal laws of the United States subsequent to the execution of this Agreement, or (c) otherwise violated any provision of this Agreement, RDC shall, in the Office's sole discretion, thereafter be subject to prosecution for any federal criminal violation, or suit for any civil cause of action, of which the Office has knowledge, including but not limited to a prosecution or civil action based on the Information, the Statement of Facts, the conduct described therein, or perjury and obstruction of justice. Any such prosecution or civil action may be premised on any information provided by or on behalf of RDC to the Office or DEA at any time. In any such prosecution or civil action, it is understood that: (a) no charge or claim would be time-barred provided that such prosecution or civil action is brought

within the applicable statute of limitations period, excluding the period from the execution of this Agreement until its termination; (b) RDC agrees to toll, and exclude from any calculation of time, the running of the applicable statute of limitations for the length of this Agreement starting from the date of the execution of this Agreement and including any extension of the period of deferral of prosecution pursuant to paragraphs 16 through 18 below; and (c) RDC waives any objection to venue with respect to any charges arising out of the conduct described in the Statement of Facts and consents to the filing of such charges in the Southern District of New York. By this Agreement, RDC expressly intends to and hereby does waive its rights in the foregoing respects, including any right to make a claim premised on the statute of limitations, as well as any constitutional, statutory, or other claim concerning pre-indictment delay. Such waivers are knowing, voluntary, and in express reliance on the advice of RDC's counsel.

15. It is further agreed that in the event that the Office, in its sole discretion, determines that RDC has violated any provision of this Agreement, including by failure to meet its obligations under this Agreement: (a) all statements made or acknowledged by or on behalf of RDC to the Office or DEA, including but not limited to the Statement of Facts, or any testimony given by RDC or by any agent of RDC before a grand jury, or elsewhere, whether before or after the date of this Agreement, or any leads from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings hereinafter brought by the Office against RDC; and (b) RDC shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule, that statements made or acknowledged by or on behalf of RDC before or after the date of this Agreement, or any leads derived therefrom, should be suppressed or otherwise excluded from evidence. It is the intent of this Agreement to waive any and all rights in the foregoing respects.

16. RDC agrees that, in the event that the Office determines during the period of deferral of prosecution described in paragraphs 10 and 12 above (or any extensions thereof) that RDC has violated any provision of this Agreement, an extension of the period of deferral of prosecution may be imposed in the sole discretion of the Office, up to an additional one year, but in no event shall the total term of the deferral-of-prosecution period of this Agreement exceed six (6) years. Any extension of the deferral-of-prosecution period extends all terms of this Agreement for an equivalent period.

17. RDC, having truthfully admitted to the facts in the Statement of Facts, agrees that it shall not, through its attorneys, agents, or employees, make any statement, in litigation or otherwise, contradicting the Statement of Facts or its representations in this Agreement. Consistent with this provision, RDC may raise defenses and/or assert affirmative claims and defenses in any proceedings brought by private and/or public parties as long as doing so does not contradict the Statement of Facts or such representations. Any such contradictory statement by RDC, its present or future attorneys, agents, or employees shall constitute a violation of this Agreement and RDC thereafter shall be subject to prosecution as specified in paragraphs 14 through 15, above, or the deferral-of-prosecution period shall be extended pursuant to paragraph 16, above. The decision as to whether any such contradictory statement will be imputed to RDC for the purpose of determining whether RDC has violated this Agreement shall be within the sole discretion of the Office. Upon the Office's notifying RDC of any such contradictory statement, RDC may avoid a finding of violation of this Agreement by repudiating such statement both to the recipient of such

statement and to the Office within four business days after having been provided notice by the Office. RDC consents to the public release by the Office, in its sole discretion, of any such repudiation. Nothing in this Agreement is meant to affect the obligation of RDC or its officers, directors, agents or employees to testify truthfully to the best of their personal knowledge and belief in any proceeding. Nothing in paragraph 17 applies to statements made, in litigation or otherwise, by any present or former officers, directors, agents or employees of RDC that are made solely in an individual capacity, and not on behalf of RDC.

18. RDC agrees that it is within the Office's sole discretion to choose, in the event of a violation, the remedies contained in paragraphs 14 and 15 above, or instead to choose to extend the period of deferral of prosecution pursuant to paragraph 16, provided, however, that if RDC's violation of this Agreement is limited to an untimely payment of the Stipulated Forfeiture Amount, the Office may elect instead to choose the additional financial penalties set forth in paragraph 6, above. RDC understands and agrees that the exercise of the Office's discretion under this Agreement is unreviewable by any court. Should the Office determine that RDC has violated this Agreement, the Office shall provide notice to RDC of that determination and provide RDC with an opportunity to make a presentation to the Office to demonstrate that no violation occurred, or, to the extent applicable, that the violation should not result in the exercise of those remedies or in an extension of the period of deferral of prosecution, including because the violation has been cured by RDC.

Corporate Governance

19. RDC's Board of Directors (the "Board") shall establish and maintain a standing Controlled Substances Compliance Committee (the "CSCC"), in accordance with the procedures set forth below.

20. Pursuant to Section 61(d) of the Cooperative Corporations Law of the State of New York, RDC will propose to its voting members that RDC's by-laws be amended to permit RDC's current directors (the "Board") to appoint at least two independent directors (the "Independent Directors") to serve the interest of the general public (the "Proposed Amendment"). No director shall qualify as "independent" unless the Board affirmatively determines that the director has no material relationship with RDC, either directly or indirectly, as an employee, shareholder, member, officer, or customer of RDC. In the event that RDC subsequently expands the size of the Board, it will appoint additional Independent Directors to the Board in an amount consistent with Section 61 of New York Cooperative Corporations Law. In the event that RDC subsequently contracts the size of the Board, it shall retain at least two Independent Directors.

21. If the Proposed Amendment is successful, the CSSC must, at a minimum, consist of two Independent Directors at all times. RDC management and the Board shall use best efforts to ensure passage of the Proposed Amendment, including (a) educating RDC voting members as to the reasons for adopting the Proposed Amendment, and (b) publicizing to RDC voting members a Board resolution recommending that RDC members vote in favor of the Proposed Amendment.

22. If, however, the Proposed Amendment fails to obtain the necessary 2/3rds vote of its membership required for passage under RDC's by-laws, RDC shall create or maintain a CSCC

in the form of an advisory committee to the Board. Any Advisory CSCC shall be composed of an existing director or directors of the Board, plus two individuals not affiliated with RDC that are to be selected by the Board for their industry and compliance experience. One of these outside advisers shall serve as the Committee Chair. At least one outside advisor must have specific expertise in the field of compliance with controlled substances regulations and policies (the Subject Matter Expert, or "SME"). Before seeking passage of the Proposed Amendment, RDC may, at its discretion, establish an Advisory CSCC. If RDC does so, any outside advisors serving on the Advisory CSCC shall be considered "independent" for purposes of appointment as Independent Directors on a CSCC, notwithstanding their receipt of consideration for their service as outside advisors on the Advisory CSCC.

23. Regardless of whether the CSCC contains Independent Directors, or outside advisory consultants, the CSCC shall report regularly to the full Board on compliance issues, and shall regularly review the reports from, and interact with, the Independent Monitor, as is necessary to comply with the terms of this Agreement. In addition, the CSSC, as well as the full Board, shall have access to timely legal advice, and shall be regularly advised by counsel regarding all aspects of RDC's compliance with the Controlled Substances Act, its implementing regulations, and this Agreement.

24. RDC's chief compliance officer ("CCO") shall regularly report to the Board or, alternatively, the CSCC. The Board, including the CSCC, shall be empowered with broad authority to retain outside consultants, compliance services, legal advisors, and/or auditors as necessary to ensure RDC's compliance with all requirements of the Controlled Substances Act, its implementing regulations, and this Agreement. The Board, including the CSCC, shall oversee compliance decisions and RDC management's compliance team.

25. The CSCC shall also review RDC's Controlled Substances Monitoring Program requirements, and every two years recommend to the full Board any necessary updates of systems or procedures to ensure that the CSMP remains current and in compliance with all federal and state regulations. As part of this review, the CSCC shall update RDC's CSMP manual, and shall report to the Board on evolving or new technologies, including improved data analysis, that could be utilized to improve RDC's suspicious order reporting systems.

26. During the term of this Agreement, RDC shall promptly notify the Office of any changes to the membership of the Board or RDC's executive team, including but not limited to the addition or removal of an individual, or a change in an individual's title or responsibility.

Compliance Program

27. RDC represents that it has implemented and will continue to implement and maintain an effective compliance program designed to prevent and detect violations of the Controlled Substances Act, its implementing regulations, and the directives and orders of any United States regulator, including without limitation the DEA. In order to address deficiencies in its compliance controls, policies, and procedures, RDC shall maintain and implement a Controlled Substances Monitoring Program (the "CSMP") that meets the requirements set forth in the compliance addendum (the "Compliance Addendum") (a copy of which is attached as Exhibit D).

28. It is understood that RDC shall promptly notify the Office of (a) any deficiencies, failings, or matters requiring attention with respect to RDC's adoption, implementation, or maintenance of the compliance programs described in the Compliance Addendum; and (b) any steps taken or planned to be taken by RDC to address the identified deficiency, failing, or matter requiring attention. RDC's failure to adopt, implement, or maintain a CSMP as described in the Compliance Addendum shall constitute a violation of this Agreement.

Independent Monitor

29. RDC will implement the provisions regarding the Independent Monitor, as required in the addendum attached as Exhibit E.

DEA Registration

30. RDC shall comply with any and all terms of the DEA letter agreement regarding its Controlled Substances Act registration (the "DEA Letter Agreement") entered into between DEA and RDC (a copy of which is attached as Exhibit F). Nothing about the DEA Letter Agreement shall in any way modify the terms of this Agreement or shall be construed as a condition precedent for enforcing any term of this Agreement. In the event of a conflict between the terms of the DEA Letter Agreement and this Agreement, the terms of this Agreement shall control.

Limits of this Agreement

31. It is understood that this Agreement is binding on the Office and the DEA but does not bind any other Federal agencies, any state or local law enforcement agencies, any licensing authorities, or any regulatory authorities. However, if requested by RDC or its attorneys, the Office will bring to the attention of any such agencies, including but not limited to any regulators, as applicable, this Agreement, the cooperation of RDC, and RDC's compliance with its obligations under this Agreement.

Sale, Merger, or Insolvency of RDC

32. Except as may otherwise be agreed by the parties hereto in connection with a particular transaction, RDC agrees that in the event it sells, merges, or transfers all or substantially all of its business operations as they exist as of the date of this Agreement, whether such sale is structured as a sale, asset sale, merger, or transfer, it shall include in any contract for sale, merger or transfer a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. However, the terms of this Agreement shall not be construed to apply to that portion of any purchaser's or successor in interest's assets or operations that are unrelated to RDC's assets or operations. The Government shall consider any request by RDC that the Government, in its sole discretion, waive the requirement that all provisions in this paragraph bind RDC and/or any of its purchasers or any successors in interest.

33. RDC also represents and warrants that it has reviewed its financial situation, that it currently is not insolvent as such term is defined in 11 U.S.C. § 101(32), and that it reasonably believes that it shall remain solvent following payment to the Government of the Stipulated Forfeiture Amount. Further, RDC and the Government warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to RDC, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which RDC was or became indebted to on or after the Effective Date, within the meaning of 11 U.S.C. § 548(a)(1).

34. If within 91 days of the Effective Date of this Agreement or any payment made under this Agreement, RDC commences any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors or a third party commences any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of RDC's debts, or seeking to adjudicate RDC as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for RDC or for all or part of RDC's assets, RDC agrees as follows:

a. RDC's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and RDC shall not argue or otherwise take the position in any such case, action, or proceeding that (i) RDC's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) RDC was insolvent at the time this Agreement was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to RDC.

b. If any of RDC's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its option, may rescind the Agreement and bring any criminal, civil and/or administrative claim, action, or proceeding against RDC for the claims that would otherwise be covered by the release in Paragraph 13 above. RDC agrees that (i) any such charge, claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the charge, case, action, or proceeding described in the first sentence of this Paragraph, and RDC shall not argue or otherwise contend that the Government's charge, claim, action, or proceeding is subject to an automatic stay; (ii) RDC shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any charge, claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to RDC that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the date of execution of this Agreement; and (iii) the Government has a valid claim against RDC in the amount of the Stipulated Forfeiture Amount and the Government may pursue its charge, claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding.

c. RDC acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

Civil Settlement Agreement and Integration Clause

35. This Agreement sets forth all the terms of the Deferred Prosecution Agreement between RDC and the Office. No modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Office, RDC's attorneys, and a duly authorized representative of RDC.

36. RDC shall comply with any and all terms of the Stipulation and Order of Settlement and Dismissal (the "Civil Settlement Agreement") entered into between the Civil Division of this Office and RDC (a copy of which is attached as Exhibit G).

37. Nothing about the Civil Settlement Agreement shall in any way modify the terms of this Agreement or shall be construed as a condition precedent for enforcing any term of this Agreement. In the event of a conflict between the terms of the Civil Settlement Agreement and this Agreement, the terms of this Agreement shall control.

Public Filing

38. RDC and the Office agree that, upon the submission of this Agreement (including the Statement of Facts and other attachments) to the Court, this Agreement and its attachments shall be filed publicly in the proceedings in the United States District Court for the Southern District of New York.

39. The parties understand that this Agreement reflects the unique facts of this case and is not intended as precedent for other cases.

Execution in Counterparts

40. This Agreement may be executed in one or more counterparts, each of which shall be considered effective as an original signature. Further, all facsimile and digital images of signatures shall be treated as originals for all purposes.

GEOFFREY S. BERMAN
United States Attorney
Southern District of New York

By: _____
Stephanie Lake
Louis Pellegrino
Nicolas Roos
Alexandra Rothman
Assistant United States Attorneys

_____
LAURA GROSSFIELD BIRGER
Chief, Criminal Division

Accepted and agreed to:

_____
John Kinney
Interim Chief Executive Officer
Rochester Drug Co-operative

_____
Douglas B. Farquhar, Esq.
Attorney for Rochester Drug Co-operative

EXHIBIT A

ROCHESTER DRUG CO-OPERATIVE, INC.

Unanimous Resolution of Rochester Drug Co-operative Board of Directors

The undersigned, being all of the directors (the "Directors") of ROCHESTER DRUG CO-OPERATIVE, INC., a New York Domestic Cooperative Corporation (hereafter "RDC" or the "Company"), pursuant to Section 14 of the Cooperative Corporations Law of the State of New York and the internal regulations of the Company, hereby consent to the adoption of the following resolution authorizing the Company to enter into a Deferred Prosecution Agreement and associated agreements with the Office of the United States Attorney for the Southern District of New York (the "Office") to resolve potential criminal, civil, and administrative actions against RDC relating to charges that RDC: (a) conspired to distribute narcotics in a manner not authorized by law, in violation of 21 U.S.C. § 846, (b) conspired to defraud the Drug Enforcement Administration ("DEA"), in violation of 18 U.S.C. § 371, and (c) failed to report suspicious orders to the DEA, as required by 21 U.S.C. §§ 842(a)(5) and 871(b), and 21 C.F.R. § 1301.74(b):

> WHEREAS, the Directors understand and believe each of the following to the best of their knowledge;
>
> WHEREAS, RDC is a New York Domestic Cooperative Corporation engaged in the wholesale distribution of retail pharmacy and home healthcare products, and is a DEA-registered distributor of Schedule II through V controlled substances pursuant to the Controlled Substances Act, 21 U.S.C. §§ 801 et seq. ("the CSA");
>
> WHEREAS, the Directors understand that the Office and the DEA have been investigating RDC for the aforementioned violations of the CSA (the "CSA Violations"), and RDC has been notified by the Office that in the absence of any plea, deferred prosecution agreement, civil settlement, or administrative resolution, the Government intends to file criminal, civil, and administrative charges against RDC for the CSA Violations;

WHEREAS, the Office has informed RDC of its willingness to resolve the potential criminal, civil, and administrative charges against RDC in the form of a Deferred Prosecution Agreement ("DPA"), Stipulated Forfeiture Agreement, Criminal Information, Civil Settlement, Compliance Addendum, Monitoring Agreement, Statement of Facts, and other associated documents (collectively, the "DPA and Associated Agreements") to resolve all charges against RDC, on the terms contained within those documents;

WHEREAS, the Directors have reviewed the DPA and Associated Agreements;

WHEREAS, the Directors have determined, after review and due consideration, that it is in the best interest of the Company to enter into a Deferred Prosecution Agreement, pay the Stipulated Forfeiture Amount, stipulate to the accuracy of the Statement of Facts, and agree to all other provisions, including corporate governance and CSA-related compliance provisions, contained within the DPA and Associated Agreements;

NOW THEREFORE, pursuant to the governing documents of the Company and the laws of the State of New York;

IT IS RESOLVED, that RDC and its management thereof is hereby authorized to take any and all action required on behalf of the Company to:

(1) Enter into and execute the DPA and Associated Agreements, including the Statement of Facts, on behalf of the Company;

(2) Acknowledge the filing of the Information, authorize RDC Interim Chief Executive Officer John Kinney to waive indictment on behalf of RDC and act as RDC's authorized agent in court proceedings related to the DPA, and accept the monetary penalty set forth in the DPA and Associated Agreements;

(3) Cooperate fully with the Government in any and all CSA-related investigations;

(4) Pay all stipulated forfeiture amounts, as well as expend all necessary funds for the improvement and maintenance of CSA compliance functions at RDC;

(5) Effectuate all corporate governance changes necessary to comply with the terms of the DPA and Associated Agreements, including taking steps to amend the corporate by-laws to nominate independent directors and/or institute a corporate compliance committee;

(6) Take any and all further action necessary to effectuate the purpose and intent of the DPA and Associated Agreements, as well as any action necessary to ensure RDC's on-going compliance with all state and federal laws relating to the distribution and sale of controlled substances.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the undersigned Directors, in the capacity listed below, executed this consent as of the 20th day of April, 2019.

Rochester, New York.

Paul B. Pagnotta

Garry Mrozek

Christopher K. Casey

Stephen L. Giroux

Joseph P. Lech

Don Arthur, Jr.

Richard Klenk

Boris Mantell

EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA	:	
- v. -	:	**INFORMATION**
ROCHESTER DRUG CO-OPERATIVE, INC.,	:	19 Cr.
Defendant.	:	

COUNT ONE
(Narcotics Conspiracy)

The United States Attorney charges:

The Defendant

1. At all times relevant to this Information, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, was a wholesale distributor of pharmaceutical products, including controlled substances, headquartered in Rochester, New York. At various times relevant to this Information, ROCHESTER DRUG CO-OPERATIVE, INC. was one of the nation's ten largest distributors of pharmaceutical products with over 1,300 pharmacy customers and over $1 billion in revenue per year.

Overview

2. For at least half a decade, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, distributed dangerous, highly addictive opioids to pharmacy customers that it knew were being sold and used illicitly. Among other things, and at the direction of senior

management, ROCHESTER DRUG CO-OPERATIVE, INC. supplied large quantities of oxycodone, fentanyl, and other dangerous opioids to pharmacy customers that its own compliance personnel determined were dispensing those drugs to individuals who had no legitimate medical need for them. The company's chief executive officer ("Executive-1") and other members of senior management directed the company to supply pharmacies they knew were dispensing controlled substances in contravention of the Controlled Substances Act ("CSA"), in order to maximize the company's revenues and the compensation of Executive-1.

3. To perpetuate this scheme, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, acted in violation of the CSA and its own purported polices in an effort to conceal its illicit distribution of controlled substances from the Drug Enforcement Administration ("DEA") and other law enforcement authorities. Among other things, ROCHESTER DRUG CO-OPERATIVE, INC. made the deliberate decision not to investigate, monitor, and report to the DEA pharmacy customers that it knew were diverting controlled substances for illegitimate use. Because it knew that reporting these pharmacies would likely result in the DEA investigating and shutting down its customers, ROCHESTER DRUG CO-OPERATIVE, INC.'s senior management directed the company's compliance department not to report them, and instead to continue supplying those customers with dangerous controlled

substances that the company knew were being dispensed and used for illicit purposes.

The Opioid Epidemic

4. Over the past decade, the United States has seen a dramatic rise in the use and abuse of oxycodone and fentanyl, two highly addictive, narcotic-strength opioids. These opioids are used to treat severe and chronic pain conditions, such as post-operative pain, serious back and orthopedic injuries, as well as pain associated with certain forms of cancer and other terminal illnesses. Oxycodone, which is distributed as a pill, and fentanyl, which is distributed as a patch or spray, can only be obtained from pharmacies with a prescription written by a treating physician.

5. Because of their highly addictive qualities, opioids such as oxycodone and fentanyl are frequently abused, which abuse can lead to opioid dependence, addiction, and the use of illicit narcotics such as heroin. For example, in 2016 -- *i.e.*, during the time period relevant to this Information -- approximately 2.1 million people in the United States suffered from substance abuse disorders related to prescription opioid pain relievers such as oxycodone and fentanyl. In the same year, approximately one-quarter of patients who were prescribed opioids for chronic pain abused them, and approximately 80% of individuals who used heroin

first abused prescription opioids. Because they are highly addictive and available pursuant only to a prescription, oxycodone and fentanyl products have enormous cash value to drug dealers who sell oxycodone pills or fentanyl products to addicted individuals on the street for thousands of dollars.

Responsibilities under the Federal Narcotics Laws

6. The CSA regulates the manufacturing, distribution, and use of substances that can have a detrimental effect on public health and welfare. See 21 U.S.C. § 801, et seq. Some of those controlled substances, including opioids such as oxycodone and fentanyl, may be manufactured, distributed, or used lawfully in accordance with the requirements and limitations of the CSA.

7. To distribute controlled substances like oxycodone and fentanyl, a company such as ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, must register with the DEA and comply with laws and regulations imposed by the CSA.

8. As a registered distributor, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, is required to maintain "effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). As a registered distributor, ROCHESTER DRUG CO-OPERATIVE, INC. is also responsible for reporting suspicious orders to the DEA, which are defined by

regulation as including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

9. Throughout the time period relevant to this Information, the DEA was responsible for enforcing the CSA and its implementing regulations including by, among other things, approving distributors' registrations, conducting audits and inspections, reviewing sales data and suspicious order reports, and bringing enforcement actions against registrants who failed to comply with the CSA.

10. At various times relevant to this Information, and as required by the CSA and its implementing regulations, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, promulgated policies purported to control against diversion of controlled substances and report suspicious orders to the DEA. ROCHESTER DRUG CO-OPERATIVE, INC. informed the DEA of these policies and, from time to time, provided copies of those policies to the DEA.

11. At various times relevant to this Information, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, also notified its customers that it was required to report suspicious orders for controlled substances to the DEA, and that it would not ship orders that were deemed suspicious.

The Company's Unlawful Distribution of Controlled Substances

12. Between in or about 2012 and in or about March 2017, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, violated the federal narcotics laws by distributing to its pharmacy customers controlled substances - including dangerous opioids such as oxycodone and fentanyl - that the company knew were being sold and used illicitly. The company did so to, among other things, maximize the company's revenues and the compensation of Executive-1.

13. Specifically, many pharmacy customers of ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, displayed the "red flags" that, according to the company's own policies, "indicate that a pharmacy may be dispensing controlled substances for other than legitimate medical purposes" to individuals who were diverting or abusing the substances. These "red flags" included, among other things, pharmacies that were "[d]ispensing highly-abused controlled substances" in large quantities, purchasing "only controlled substances and little else," "[d]ispensing quantities consistently higher than accepted medical standards," "[a]ccepting a high percentage of cash from patients," "[d]ispensing to out-of-area or out-of-state patients," and "[f]illing controlled substance

prescriptions issued by practitioners acting outside the scope of their medical practice or specialty."

14. Throughout the relevant time period, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, dispensed controlled substances to customers that its own compliance department had concluded displayed these "red flags" and others. The compliance department repeatedly reported to senior management -- including Executive-1 -- that many of its largest customers were dispensing controlled substances that were being diverted. Nonetheless, Executive-1 directed the compliance department and sales personnel to continue supplying these pharmacies with oxycodone, fentanyl, and other controlled substances.

15. In almost every case, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, continued to distribute controlled substances to the pharmacies it identified as displaying "red flags" of diversion even after becoming aware of these problems. In fact, in many cases, the company continued to distribute controlled substances to problematic customers for years after learning of the "red flags" associated with the pharmacy, and often only terminated their business with those customers after learning that the customer - or ROCHESTER DRUG CO-OPERATIVE, INC. itself - was under DEA investigation.

16. For example, at various times relevant to this Information, the compliance and sales staff at ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, repeatedly informed senior management that they were troubled by the large quantities of controlled substances being purchased by some of the company's customers. In 2013, for instance, the company's head of sales observed to Executive-1, the company's chief operating officer ("Executive-2"), and the chief compliance officer (the "Compliance Officer") that "we have some VERY suspicious customers due to their buying" of large quantities of controlled substances. On another occasion, one of the company's compliance auditors told Executive-2 and the Compliance Officer that some pharmacies' "very high" controlled substance dispensing averages were "like a stick of dynamite waiting for [the] DEA to light the fuse." In both cases, the company continued to supply the customers with controlled substances and did not report the pharmacies to the DEA.

17. Similarly, the Compliance Officer and other employees in the compliance department repeatedly noted, including to Executive-1 and Executive-2, that their customers were filling prescriptions written by doctors that were under DEA investigation or had been indicted. For instance, a member of the compliance staff noted to the Compliance Officer and others that a pharmacy was filling prescriptions written by multiple doctors on the

company's "watch list," and the prescribers themselves were "a large concern of RED FLAG diversion."

18. ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, also supplied pharmacies that it knew were dispensing controlled substances to patients traveling to the pharmacies from out-of-state and who were paying for controlled substances in cash, both of which are red flags that the patients using those controlled substances had no legitimate medical need for them. For instance, in 2012, the company began supplying a pharmacy that admitted it did not do any due diligence on its opioid prescriptions. That pharmacy previously had a customer die of a drug overdose. By 2014, the company observed that over sixty percent of the prescriptions filled by the pharmacy were paid for in cash and nearly all cash-paying patients were traveling to the pharmacy from out of state. One of ROCHESTER DRUG CO-OPERATIVE, INC.'s compliance auditors described the pharmacy as a "DEA investigation in the making," to which Executive-1 commented, "I don't think this is going to end well." Nonetheless, ROCHESTER DRUG CO-OPERATIVE, INC. continued to supply the pharmacy with controlled substances for another four years, and did not stop supplying the pharmacy until 2018, after the DEA began its criminal investigation of ROCHESTER DRUG CO-OPERATIVE, INC.

19. The continued distribution of controlled substances by ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, to these customers that it knew were dispensing the narcotics for illicit purposes was directed by the company's senior management, including Executive-1, despite a clear understanding by the company's senior management that the pharmacies' dispensing practices were in contravention of the CSA. In fact, in 2014, a compliance consultant instructed the company's senior management, including Executive-1 and Executive-2, that "[a]s a distributor, [the company] need[ed] to comply with the DEA 'Know-Your-Customer' Due Diligence policy" and warned that the company would be placed in the DEA's "cross-hairs . . . because of [its] willful blindness and deliberate ignorance." Later that year, the company's outside legal counsel noted that ROCHESTER DRUG CO-OPERATIVE had over one hundred pharmacy customers that required additional due diligence to ensure they were dispensing controlled substances in compliance with the law. Nonetheless, the company largely ignored these warnings and continued to distribute controlled substances to customers that were illegitimately dispensing those narcotics.

Statutory Allegation

20. From at least in or about January 2012, up to and including in or about March 2017, in the Southern District of New York and elsewhere, ROCHESTER DRUG CO-OPERATIVE, INC., the

defendant, and others known and unknown, intentionally and knowingly did combine, conspire, confederate, and agree together and with each other to violate the narcotics laws of the United States.

21. It was a part and an object of the conspiracy that ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, and others known and unknown, would and did distribute and possess with intent to distribute controlled substances, outside the scope of professional practice and not for a legitimate medical purpose, in violation of 21 U.S.C. § 841(a)(1).

22. The controlled substances that ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, and others known and unknown, conspired to distribute and possess with intent to distribute were (i) a quantity of mixtures and substances containing a detectable amount of oxycodone, in violation of 21 U.S.C. § 841(b)(1)(C), and (ii) 400 grams and more of mixtures and substances containing a detectable amount of fentanyl, in violation of 21 U.S.C. § 841(b)(1)(A).

(Title 21, United States Code, Section 846.)

COUNT TWO
(Conspiracy to Defraud the United States)

The United States Attorney further charges:

23. The allegations contained in paragraphs 1 through 22 of this Information are repeated and realleged as if fully set forth herein.

The Scheme to Defraud the DEA

24. Between in or about 2012 and in or about March 2017, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, sought to obstruct and hinder DEA oversight of the company's practices in order to prevent the DEA's enforcement of the narcotics laws against ROCHESTER DRUG CO-OPERATIVE, INC. and its customers. Despite the statutory and regulatory requirements that ROCHESTER DRUG CO-OPERATIVE, INC. guard against diversion and report suspicious orders to the DEA, ROCHESTER DRUG CO-OPERATIVE, INC. made material misrepresentations to the DEA about its due diligence practices and controls against diversion, and did not report thousands of suspicious orders from its customers to the DEA.

25. In order for the DEA to properly oversee the distribution of controlled substances and carry out its mandate under the CSA and implementing regulations, distributors -- such as ROCHESTER DRUG CO-OPERATIVE, INC., the defendant -- are required to monitor their customers by investigating suspicious activity and reporting such activity to the DEA. Beginning in or about 2007, the DEA

notified ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, in writing that it was required by law to maintain a program to guard against diversion of controlled substances by its customers, and needed to report to the DEA those orders and customers that appeared suspicious.

26. ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, created standard operating procedures for the detection and reporting of diversion of controlled substances because it was required to do so by law. Specifically, in response to that directive, on multiple occasions during the relevant time period, ROCHESTER DRUG CO-OPERATIVE, INC. represented to the DEA that it had standard operating procedures for conducting due diligence on new customer accounts and reporting suspicious orders to the DEA. On multiple occasions, including during DEA audits and in connection with ROCHESTER DRUG CO-OPERATIVE, INC.'s application for a license to operate a new facility in Fairfield, New Jersey, the company provided the DEA with copies of its due diligence and suspicious order reporting standard operating procedures. Among other things, ROCHESTER DRUG CO-OPERATIVE, INC.'s standard operating procedures relating to customer due diligence represented that it would conduct due diligence on new customer accounts prior to selling new customers controlled substances. In addition, the company's standard operating procedures relating to

suspicious order reporting represented that the company would report orders in a manner consistent with the DEA's regulations.

27. Despite these representations to the DEA, as well as the statutory and regulatory obligations on distributors of controlled substances, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, acted in direct contravention of, among other things, the policies that the company shared with the DEA and represented it followed. It did so at the explicit direction of senior management -- including Executive-1, Executive-2, and the Compliance Officer -- and in order to continue doing business with customers it knew were likely diverting controlled substances.

Misrepresentations About the Company's Due Diligence

28. First, despite the statutory obligation that ROCHESTER DRUG CO-OPERATIVE, the defendant, maintain effective controls against diversion, and the company's specific representations to the DEA that it would conduct due diligence on new customer accounts before opening them by, among other things, reviewing multiple months' worth of controlled substance dispensing data, the company opened multiple new accounts without conducting any due diligence. ROCHESTER DRUG CO-OPERATIVE, INC. acted in this manner, notwithstanding its representations, at the direction of its senior management, and in particular Executive-1 and Executive-2. For example, in or about July 2015, in response to

delays in new account openings, Executive-1 began pushing to open new accounts immediately, without conducting due diligence, and remarked that even though he had "no idea if this [new pharmacy customer] is a good guy or bad guy . . . it is taking too long [to open the account] no matter what the problem is." Executive-1 added in a subsequent email, "I know we have to do due diligence but we have the tail wagging the dog . . . this HAS to stop . . . Good or bad."

29. Consistent with Executive-1's directive, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, opened multiple new customer accounts without conducting due diligence in advance of making sales of controlled substances. Many of these new customers, however, had dispensing practices indicating that they were unlawfully distributing controlled substances. Indeed, as the Compliance Officer noted to other members of the compliance department, "all the new stores we are bringing on have baggage." That was, according to what another compliance department employee had heard, at least in part, because "everyone is being cut off by [other distributors] and running over to RDC . . . we are picking up rejects from other distributors." And in multiple cases, after opening new customer accounts without conducting due diligence and selling controlled substances for months, ROCHESTER DRUG CO-OPERATIVE, INC. discovered significant problems in the dispensing

records for those customers -- including high dosage opioid prescriptions and accepting a high percentage of cash from patients -- that suggested the pharmacies were unlawfully distributing controlled substances.

30. ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, intended to defraud the DEA with respect to its account opening due diligence procedure. Specifically, the decision to open new accounts without conducting due diligence, in contravention of the company's representations to the DEA, was motivated, at least in part, by a perception by the company's senior management that it could avoid DEA oversight because of changing enforcement priorities. In or about June 2016, Executive-1 told Executive-2 and the Compliance Officer that "[b]ased on recent government changed [sic] I want to accelerate our account opening process. As soon as our credit managers completely approve our credit app we will open an account right away." Executive-1 justified the change in the company's practice based on his perception that "the government has recently told the DEA to lay off wholesalers."

31. Additionally, in response to Executive-1's directive that the company open new accounts without conducting due diligence, the Compliance Officer reminded Executive-1 and Executive-2 that the company's standard operating procedure that it provided to the DEA "states that RDC will conduct a review prior

to opening [a customer] to controls," and suggested that that any change to the company's policy "be documented so we may show DEA." But in order to conceal its change in practice, the company did not amend its written policies or notify the DEA, and instead opened accounts without conducting due diligence into the new customers' ordering and prescribing practices. Compliance employees subsequently determined that some of those customers displayed "red flags" of diversion of controlled substances.

Willful Failure to File Suspicious Order Reports

32. Second, in furtherance of its scheme to defraud the DEA, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, knowingly and willfully avoided filing suspicious order reports with the DEA. The company did not report suspicious orders in order to protect the profit being generated by customers dispensing large quantities of controlled substances. Indeed, at the direction of the company's senior management, including Exective-1 and Executive-2, the Compliance Officer instructed compliance department employees by email that "we do not turn in a store" merely based on suspicions of wrongdoing by the customer, but rather choose "to educate and work with our customers."

33. Rather than reporting suspicious orders, the compliance department of ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, undertook to prevent the reporting of suspicious orders. During

the relevant time period, the company maintained an automated "order of interest" program, which flagged customer orders for controlled substances that exceeded a customer's pre-established limits based on past order size. ROCHESTER DRUG CO-OPERATIVE, INC. represented to the DEA that it used this system to identify suspicious orders. But, in fact, the company willfully avoided filing suspicious order reports. For example, the compliance department staff were instructed to mark flagged orders "not suspicious" and release orders to pharmacies without reviewing the pharmacies' dispensing data. Additionally, in order to prevent the generation of future "orders of interest," and therefore avoid reporting suspicious orders to the DEA, the company's compliance department regularly increased the threshold limit of controlled substances a pharmacy could purchase from ROCHESTER DRUG CO-OPERATIVE, INC. The company knew that such a practice was contrary to law. For example, in 2012, following a conference hosted by the DEA, a ROCHESTER DRUG CO-OPERATIVE, INC. employee told Executive-1, Executive-2, and the Compliance Officer that the DEA has stated that "if we currently have stores that are constantly hitting our suspicious order report [threshold] . . . we cannot just simply cut them back, on the drug that is causing the alert. . . . by cutting them back, we are telling the account[] [t]hat a

little bit of Diversion, is okay." Nonetheless, throughout the relevant time period, the company did just that.

34. Indeed, in some instances, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, at the direction of senior management, also eliminated customers' controlled substance order limit thresholds from the company's automated system entirely. For example, in March 2013, when ROCHESTER DRUG CO-OPERATIVE, INC.'s largest customer exceeded its order limit for oxycodone, the Compliance Officer wrote to Executive-1 and Executive-2 that while "[t]echnically by our [standard operating procedure] we should make a call and stop selling," the company continued to supply controlled substances to the customer.

35. Even after ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, terminated pharmacy customers for failing to comply with the CSA, the company did not report those customers to the DEA.

36. Despite its obligations under the CSA and its representations in its own policies and to the DEA, during the relevant time period, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, only filed four suspicious order reports with the DEA. During the same period, however, the company should have reported hundreds of suspicious orders to the DEA, including orders associated with customers that the company's compliance department

determined had "red flags," or customers that were terminated, but it instead knowingly and willfully failed to do so.

Statutory Allegation

37. From at least in or about January 2012, up to and including in or about March 2017, in the Southern District of New York and elsewhere, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, and others known and unknown, willfully and knowingly combined, conspired, confederated, and agreed together and with each other to defraud the United States and an agency thereof, to wit, the DEA, in violation of Title 18, United States Code, Section 371.

38. It was a part and an object of the conspiracy that ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, and others known and unknown, willfully and knowingly, using deceit, craft, trickery, and dishonest means, would and did defraud the United States and an agency thereof, to wit, the DEA, by willfully failing to report suspicious orders of controlled substances to the DEA and advise the DEA of customers diverting controlled substances, thereby impeding, impairing, defeating and obstructing the lawful function of the agency, in violation of Title 18, United States Code, Section 371.

Overt Acts

39. In furtherance of the conspiracy and to effect its illegal objects, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, and its co-conspirators, committed the following overt acts, among others, in the Southern District of New York and elsewhere:

a. During the relevant time period, ROCHESTER DRUG CO-OPERATIVE, INC. received over 8,000 "orders of interest," including at least 412 flagged orders of fentanyl and 2,530 flagged orders of oxycodone, from its pharmacy customers. During that time period, however, ROCHESTER DRUG CO-OPERATIVE, INC. reported only four suspicious orders to the DEA.

b. During the relevant time period, ROCHESTER DRUG CO-OPERATIVE, INC. opened new customer accounts for customers located in the Southern District of New York and elsewhere, and sold those customers controlled substances, without conducting due diligence on the customers, as ROCHESTER DRUG CO-OPERATIVE, INC. had represented to the DEA that it would do.

c. During the relevant time period, ROCHESTER DRUG CO-OPERATIVE, INC. supplied customers located in the Southern District of New York and elsewhere with controlled substances, despite knowing that those controlled substances were being distributed outside the scope of professional practice and not for a legitimate medical purpose, and failed to report those customers

to the DEA.

(Title 18, United States Code, Section 371.)

COUNT THREE
(Failure to File Suspicious Order Reports)

The United States Attorney further charges:

40. The allegations contained in paragraphs 1 through 36 of this Information are repeated and realleged as if fully set forth herein.

41. From at least in or about January 2012, up to and including in or about March 2017, in the Southern District of New York and elsewhere, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, knowingly failed to make, keep, and furnish a record, report, notification, declaration, order and order form, statement, invoice, and information required by the Controlled Substances Act and its implementing regulations, to wit, ROCHESTER DRUG CO-OPERATIVE, INC. knowingly failed to disclose suspicious orders of controlled substances to the DEA, in violation of Title 21, United States Code, Sections 842(a)(5) and (c)(2)(A).

(Title 21, United States Code, Sections 842(a)(5) and (c)(2)(A).)

FORFEITURE ALLEGATION

42. As a result of committing the offense alleged in Count One of this Information, ROCHESTER DRUG CO-OPERATIVE, INC., the defendant, shall forfeit to the United States pursuant to Title

21, United States Code, Section 853, any and all property constituting, or derived from, any proceeds obtained, directly or indirectly, as a result of said offense and any and all property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, said offense, including but not limited to a sum of money in United States currency representing the amount of proceeds traceable to the commission of said offense that the defendant personally obtained.

Substitute Asset Provision

43. If any of the above-described forfeitable property, as a result of any act or omission of the defendant: (a) cannot be located upon the exercise of due diligence; (b) has been transferred or sold to, or deposited with, a third party; (c) has been placed beyond the jurisdiction of the court; (d) has been substantially diminished in value; or (e) has been commingled with other property which cannot be divided without difficulty; it is the intention of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the above forfeitable property.

(Title 21, United States Code, Section 853.)

Geoffrey S. Berman

GEOFFREY S. BERMAN
United States Attorney

Form No. USA-33s-274 (Ed. 9-25-58)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

ROCHESTER DRUG CO-OPERATIVE, INC.,

Defendant.

INFORMATION

19 Cr.

(18 U.S.C. 371;
21 U.S.C. §§ 842 and 846)

GEOFFREY S. BERMAN
United States Attorney

EXHIBIT C

INTRODUCTION

1. The following Statement of Facts is incorporated by reference as part of the deferred prosecution agreement (the "Agreement") between the United States Attorney's Office for the Southern District of New York (the "Office") and Rochester Drug Co-operative, Inc. ("RDC").

2. The parties agree and stipulate that the information contained in this Statement of Facts is true and accurate.

OVERVIEW

3. RDC is a regional wholesale drug cooperative, headquartered in Rochester, New York, that distributes, among other things, controlled substances to independently owned pharmacies in several states. During the relevant time period, RDC was the fourth largest wholesale distributor in New York and one of the nation's ten largest distributors, with over 1,300 pharmacy customers and over $1 billion in revenue.

4. RDC's conduct, as described herein, violated Title 21, United States Code, Sections 841 and 846, because RDC distributed controlled substances to pharmacies that it knew were dispensing controlled substances for illegitimate purposes, and to pharmacies that it should reasonably have known and intentionally avoided confirming were dispensing controlled substances for illegitimate purposes, and Title 18, United States Code, Section 371, and Title 21, United States Code, Section 842(a)(5) and (c)(2)(A), because RDC sought to obstruct and obscure U.S. Drug Enforcement Administration ("DEA") oversight of the company's practices, including by misrepresenting to the DEA the company's due diligence practices and knowingly failing to file suspicious order reports with the DEA regarding some of RDC's customers' suspicious orders.

5. Specifically, from at least in or about January 2012, up to and including in or about March 2017, RDC violated the federal narcotics laws by distributing controlled substances – including opioids such as oxycodone and fentanyl – to pharmacy customers that RDC knew were dispensing controlled substances for illegitimate purposes, and to pharmacies that it should reasonably have known and intentionally avoided confirming were dispensing controlled substances for illegitimate purposes. Among other things, RDC dispensed controlled substances to pharmacy customers that its own compliance department had concluded displayed "red flags" associated with diversion of controlled substances, including, but not limited to, dispensing large quantities of highly-abused controlled substances, purchasing little else besides those controlled substances, dispensing controlled substances in quantities consistently higher than accepted medical standards, accepting a high percentage of cash from patients purchasing controlled substances, dispensing to out-of-area patients, filling prescriptions issued by practitioners who were on RDC's "watch list" or under DEA investigation, or being terminated by another distributor. Nonetheless, despite these warnings, RDC continued to sell controlled substances – including oxycodone and fentanyl – to these customers, opened new accounts without conducting due diligence before opening, and delayed or avoided terminating pharmacy customers that RDC knew were dispensing controlled substances for illegitimate purposes, and to pharmacies that it should reasonably have known and intentionally avoided confirming were dispensing controlled substances for illegitimate purposes.

6. Additionally, during the same period, RDC made false statements to the DEA regarding its program for maintaining controls against the diversion of controlled substances. Specifically, since at least 2007, RDC was aware that it was required by law to maintain a program to guard against diversion of controlled substances by its customers, and that RDC needed to report

to the DEA those orders and customers that appeared suspicious. RDC repeatedly represented to the DEA that it had standard operating procedures for conducting due diligence on customer accounts and reporting suspicious orders to the DEA. These statements were untrue. Rather, RDC opened new accounts for pharmacy customers without first conducting due diligence on the pharmacies; released orders of controlled substances to pharmacies that RDC believed were dispensing those controlled substances for other than legitimate medical purposes; increased order limit thresholds so that pharmacies could increase the amounts of controlled substances they were ordering from RDC; shipped orders that RDC's compliance program deemed to be suspicious; and knowingly failed to report suspicious orders to the DEA. During the relevant time period, from 2012 until 2017, RDC's senior management, including the company's chief executive officer ("Executive-1"), were involved in and directed such conduct, and concealed RDC's practices from the DEA, the company's primary regulator.

THE CONTROLLED SUBSTANCES ACT'S REQUIREMENTS

7. The Controlled Substances Act ("CSA") regulates the manufacturing, distribution, and use of substances that have a detrimental effect on public health and welfare. *See* 21 U.S.C. § 801, *et seq.* Under Title 21, United States Code, Section 841(a)(1), it is illegal to distribute a controlled substance except where an individual or entity is expressly authorized "to possess, manufacture, distribute, or dispense [controlled] substances . . . in conformity with the other provisions" of the CSA. 21 U.S.C. § 822. This form of licensure, which is referred to as a DEA registration, is required for a doctor, pharmacist, distributor, manufacturer, or other practitioner to prescribe or otherwise handle prescription controlled substances.

8. The CSA also gives the DEA the authority to administer and regulate the legitimate manufacturing, prescribing, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs, along with civil and criminal

penalties for transactions outside the legitimate chain. *See* 21 U.S.C. §§ 878, 880. As part of its grant of authority under the CSA, the DEA promulgates regulations, which are codified in the Code of Federal Regulations, to prevent the diversion of controlled substances from legitimate channels. Additionally, in order to investigate activity related to the unlawful distribution of controlled substances effectively, the DEA conducts audits, reviews distribution data provided by wholesalers, obtains reports of suspicious activity from distributors and manufacturers, and utilizes other law enforcement techniques to detect the diversion of controlled substances.

9. To combat the high potential for abuse of certain controlled substances, the CSA and DEA implementing regulations create a distribution monitoring system for those authorized to handle controlled substances, at the heart of which are registration, tracking, and reporting requirements. The CSA mandates strict adherence to a number of these requirements by any person or entity that distributes controlled substances.

10. Under the CSA, as a registered distributor, RDC is required to maintain "effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). Additionally, DEA regulations provide that distributors are required to maintain effective controls and procedures to guard against theft and diversion of controlled substance. *See* 21 C.F.R. § 1301.71. In determining whether a distributor has implemented such effective controls, the DEA looks to whether the distributor has implemented the physical and operational security requirements outlined in 21 C.F.R. §§ 1301.72-1301.76. Among the physical and operation security requirements described in that section is the requirement that a person or entity that distributes controlled substances must report suspicious orders of controlled substances. *See* 21 C.F.R. § 1301.74(b). Specifically, distributors of controlled substances must design and operate a system to disclose suspicious orders of controlled

substances, and report any discovered suspicious orders to the DEA. *See id.* Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

11. RDC was aware of these obligations. In 2006 and 2007, the DEA sent letters to all DEA-registered distributors of controlled substances, including RDC, that discussed the requirements of 21 C.F.R. § 1301.74(b) and contained guidance for the identification and reporting of suspicious orders to the DEA (the "DEA Letters"). Specifically, on or about September 27, 2006, RDC received a letter from the DEA "to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem [the] nation [was] facing." In that letter, the DEA reminded RDC of its obligation to "report suspicious orders of controlled substances," as defined in 21 C.F.R. § 1301.74(b), to the DEA, and "exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." Additionally, on or about December 27, 2007, RDC received another letter from the DEA "to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b)." In that letter, the DEA stated that the "regulation clearly indicates that it is the sole responsibility of the registrant to design and operate [a system to disclose to the registrant suspicious orders of controlled substances]." That letter concluded that "registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion."

12. From in or about 2006 up to and including 2017, RDC was also advised by DEA agents, contracted compliance auditors, speakers at industry conferences, and attorneys of the

obligations imposed on distributors to maintain effective controls against the diversion of controlled substances.

THE OPIOID EPIDEMIC

13. Since before RDC received the DEA Letters in 2006 and 2007 citing the nationwide "prescription drug abuse problem," and continuing for at least the next decade, the United States saw a dramatic rise in the use and abuse of oxycodone and fentanyl, two highly addictive, narcotic-strength opioids. These opioids, both of which are distributed by RDC, are used to treat severe and chronic pain conditions, such as post-operative pain, serious back and orthopedic injuries, as well as pain associated with certain forms of cancer and other terminal illnesses. Oxycodone, which is dispensed as a pill, and fentanyl, which is dispensed as a patch or spray, can only be obtained from pharmacies with a prescription written by a treating physician, or other authorized health care practitioner.

14. RDC's compliance department and senior management were well-aware of the highly addictive qualities and frequent abuse of opioids such as oxycodone and fentanyl, which abuse can lead to opioid dependence, addiction, and the use of illicit narcotics such as heroin. Indeed, in October 2014, an RDC sales representative shared a report from the National Institute of Health with Executive-1, the chief operating officer ("Executive-2"), and other employees in RDC's compliance and sales department, which found that "[t]he United States is in the midst of a prescription drug abuse epidemic as addiction, overdoses and deaths associated with medical drug use have risen dramatically." RDC's own employees also circulated data from the Center for Disease Control ("CDC"), the DEA, and other trade publications relating to the rampant abuse of opioids in the United States. According to a CDC report distributed within RDC's compliance department, prescription drug overdoses kill more than one American every hour, and opioid-

related deaths have reduced the average life expectancy in the United States. Between 1999 and 2017, nearly 400,000 people in the United States died from an opioid overdose. This number is on the rise; since 2015, there have been 28% more opioid related deaths in the United States. Thus, the rise in the use and abuse of opioids has, according to government data shared within RDC, resulted in the deaths of hundreds of thousands of individuals. The dramatic increase in opioid abuse has had significant collateral consequences: millions of children nationwide have a parent who suffers from opioid substance abuse and the cost of opioid treatment is a substantial financial strain on the Medicare and Medicaid programs.

15. RDC was aware of the opioid epidemic, its costs, and law enforcement's focus on preventing the diversion of controlled substances. For example, between 2012 and 2017, Executive-1, Executive-2, and the chief compliance officer (the "Compliance Officer"), among others, were routinely copied on emails discussing the opioid epidemic, and the prosecution of pharmacists for running "pill mills," and doctors for their unlawful prescribing habits. RDC was also aware that law enforcement authorities were looking to distributors, like RDC, to assist in detecting and identifying pharmacies and doctors whose dispensing and prescribing practices were contributing to the opioid epidemic. For instance, in February 2012, following the public announcement of the DEA's investigation into another distributor for violations of the CSA, Executive-1 advised his senior management team, including Executive-2 and the Compliance Officer, that RDC "need[s] to stay very low profile" to avoid drawing "media" attention "with regards to [its] distribution of controlled drugs."

THE GROWTH IN SALES BY RDC OF CONTROLLED SUBSTANCES

16. Despite the emerging consensus about the opioid epidemic, and the steady rise in opioid-related deaths, RDC's controlled substances sales grew dramatically over the relevant time

period. Beginning in 2012, RDC's total sales grew considerably, in large part due to its rapid expansion of controlled substance sales. Specifically, in 2012, RDC distributed 4,743,500 tablets of oxycodone and, in 2013, it distributed 4,442,900 tablets of oxycodone. Those oxycodone sales numbers increased dramatically over the next three years: in 2014, RDC distributed 24,031,500 tablets; in 2015, the company distributed 44,306,430 tablets; and in 2016, it distributed 42,233,650 tablets. Similarly, RDC's distribution of fentanyl grew at an exponential rate: in 2012, it distributed 63,497 dosages; in 2013, that figure increased to 660,213 dosages; in 2014 and 2015, RDC distributed, respectively, 2,287,896 and 2,377,479 dosages; and in 2016, RDC distributed 1,316,115 dosages. Over the same period of time, the percentage of RDC's revenues from sales from controlled substances listed on Schedule II of the CSA increased from 5.3% in 2012 to 10.5% in 2015. It was also during this period that RDC added larger, higher volume pharmacy customers – customers that purchased increasing amounts of controlled substances. As a result, from fiscal year 2012 through fiscal year 2016, controlled substances represented approximately 14.6 percent of RDC's revenues, for a total of approximately $1.2 billion in controlled substances sales.

17. The growth in RDC's revenues from 2012 through 2016 directly benefited RDC's largest purchasers of controlled substances. Specifically, RDC is a stock cooperative with approximately 310 shareholders, including RDC's largest pharmacy customers. On an annual basis, RDC makes distributions, called "patronage dividends," to its shareholder pharmacy customers, which are calculated based on the amount of drugs and other products that the pharmacy purchased from RDC during a year. Accordingly, the pharmacies that purchase the most from RDC receive the largest dividend payments each year. For example, for fiscal year 2015, RDC's total patronage dividend distributions were $31,068,406. In the same year, RDC's largest

customer, based in Woodbury, New York ("Pharmacy-1") – which was also one of nation's largest dispensers of Subsys, a highly-addictive fentanyl spray, – received a dividend of $10,567,921.

18. RDC's increase in controlled substance sales – and the corresponding increase in the distribution of controlled substances – also benefited Executive-1, whose compensation was directly tied to RDC's pre-patronage dividend earnings. Specifically, beginning with a nine-year contract in 2005, RDC paid Executive-1 an annual base salary of several hundred thousand dollars, plus a substantial bonus based on RDC pre-patronage dividend earnings and/or cash flow. Under a five-year contract renewal in 2014, the bonus was approximately 2.5 percent of RDC's adjusted net earnings – which was calculated before RDC's dividend was paid, and before state and federal taxes – as well as an additional bonus of one percent of RDC's net cash flow, until Executive-1 retired as CEO in 2017. As a result of this arrangement, in 2012, Executive-1 received approximately $660,093 in total compensation; in 2013, he was paid approximately $739,833; in 2014, he was paid approximately $960,214; in 2015, he was paid approximately $1,529,633; in 2016, he was paid approximately $1,501,018; and in 2017, the year he retired as CEO, Executive-1 was paid approximately $1,238,651. Executive-1's bonuses, which were never fully disclosed to the board of RDC or its shareholders, increased in amount as RDC's sales of controlled substances grew, which created a significant monetary incentive to bring on new customers that posed significant risks under the CSA.

RDC'S DIVERSION OF CONTROLLED SUBSTANCES

RDC's Policies and Procedures Regarding the Diversion of Controlled Substance

19. Since at least 2011, RDC has had policies regarding the company's procedures for preventing the diversion of controlled substances to illegitimate channels. Consistent with the CSA and DEA implementing regulations, those policies set forth due diligence to be conducted by

RDC's compliance department to identify "red flags" of diversion of controlled substances to illegitimate channels. Those policies, which were amended from time to time during the relevant period, identified "red flags" that "indicate that a pharmacy may be dispensing controlled substances for other than legitimate medical purposes" to individuals who were diverting or abusing the substances. Those "red flags" included, among other things, pharmacies that were "[d]ispensing highly-abused controlled substances" in large quantities, purchasing "only controlled substances and little else," "[d]ispensing quantities consistently higher than accepted medical standards," "[a]ccepting a high percentage of cash from patients," "[d]ispensing to out-of-area or out-of-state patients," and "[f]illing controlled substance prescriptions issued by practitioners acting outside the scope of their medical practice or specialty."

20. RDC's compliance department had primary responsibility for RDC's fulfillment of its obligations under the CSA. Up until March 2017, the compliance department was supervised by RDC's Compliance Officer, who reported directly to Executive-1 and Executive-2. After November 2013, the compliance department was staffed by one or more compliance specialists, who were tasked principally with reviewing orders and dispensing data, and field auditors, who were tasked principally with visiting pharmacies to conduct due diligence. As part of its due diligence on customer accounts, RDC's compliance staff reviewed pharmacies' DEA registrations, licenses, and account applications; the field auditors visited the pharmacies; and the compliance specialists reviewed the pharmacies' dispensing data to look for the "red flags" identified in RDC's policies. RDC's compliance staff also maintained what was referred to as a "watch list," "exclusion list," or "do not fill list" of physicians who had been arrested, investigated by state or federal government agencies, subject to state administrative proceedings, or whom RDC compliance personnel had identified as engaging in suspicious prescribing practices. RDC's

compliance specialists were trained that customer due diligence included, among other things, reviewing dispensing data to see if pharmacies were filling prescriptions written by suspect physicians on the compliance department's "watch list."

21. RDC's senior management, including Executive-1 and Executive-2, were involved in compliance decision-making and were aware of RDC's legal obligation to maintain effective controls against diversion. Specifically, on multiple occasions, the Compliance Officer, other RDC employees, RDC's counsel, contracted compliance consultants, and law enforcement officers apprised Executive-1 and Executive-2 of the company's obligations under the CSA. For example, on or about February 3, 2014, a compliance consultant instructed the company's senior management, including Executive-1 and Executive-2, that "[a]s a distributor, [the company] need[ed] to comply with the DEA 'Know-Your-Customer' Due Diligence policy," which requires RDC to collect and analyze customers' controlled substances dispensing data in order to prevent diversion. The compliance consultant further warned that the company could be placed in the DEA's "cross-hairs . . . because of [its] willful blindness and deliberate ignorance." The compliance consultant explained that RDC could be in legal jeopardy by distributing controlled substances to customers "that are dispensing controlled substances not for legitimate medical purposes, accepting controlled substances prescriptions from bad doctors or accepting 'cash' only for bad prescriptions."

22. RDC also notified its customers of its obligation under the CSA to maintain effective controls against the diversion of controlled substances to illegitimate channels, and to identify the "red flags" that RDC represented it looks for in reviewing customers' orders.

RDC Failed to Provide Necessary Resources to CSA Compliance

23. Despite RDC's obligation to maintain effective controls against the diversion of controlled substances, it failed to properly staff or provide sufficient resources to its compliance department, which was tasked with maintaining those controls against diversion. In 2012, the only individuals in the compliance department were the Compliance Officer, who had no prior experience or training in compliance, and an administrative assistant. Gradually, RDC hired additional employees, but up until 2017, RDC only had a handful of employees working in the compliance department, many of whom had little or no background in compliance.

24. In addition, from at least 2013 thorough 2016, Executive-1 complained to senior management, including Executive-2 and the Compliance Officer, about the financial burden of compliance efforts. For example, in March 2015, Executive-1 wrote to the Compliance Officer and Excutive-2 that "[I] can't believe how much we have stuck in this compliance thing . . . Remember we don't know if we are wrong or right and there is NO return on what we are doing." Likewise, in July 2015, Executive-1 wrote to senior management that the company would not "be adding any more help" to its compliance department, despite the growth in sales by RDC of controlled substances. In addition, in August 2016, Executive-1 wrote to Executive-2 and the Compliance Officer that Executive-1 was "pissed at the BS we deal with on the DEA business now and the adverse effects it has had on business over the past three years." Even after RDC's outside counsel confronted Executive-1 in 2014 and 2015 about the compliance department having insufficient resources, Executive-1 refused to hire the number of employees requested by the Compliance Officer and recommended by outside consultants.

25. As a result of Executive-1's staffing decisions, RDC's compliance department lacked the training and resources to effectively monitor RDC's sales of controlled substances, and on many occasions shipped orders of controlled substances without conducting due diligence.

RDC's Distribution of Controlled Substances to Pharmacies Engaged in Illicit Activity

26. Throughout the relevant period, RDC routinely distributed controlled substances – including opioids such as oxycodone and fentanyl – to pharmacy customers that displayed "red flags" associated with diversion of controlled substances. RDC's compliance department, and in many cases RDC's senior management, knew, should reasonably have known, and intentionally avoided confirming that those pharmacy customers were diverting controlled substances to illegitimate channels.

27. From at least 2012 through 2016, for over one hundred customers, RDC's compliance department identified "red flags" of unlawful distribution of controlled substances, but nonetheless continued to ship controlled substance orders to those customers. Indeed, in a September 2014 memorandum by RDC's outside legal counsel to Executive-1, which was prepared following meetings with the compliance department's staff and shared with Executive-2, RDC's legal counsel estimated that "approximately 125 pharmacy customers currently require further due diligence" to ensure they were dispensing controlled substances in compliance with the law.

28. Specifically, RDC's compliance department observed the following types of "red flags" – all of which were listed in RDC's due diligence policies – associated with RDC's pharmacy customers' dispensing:

a. Many of RDC's customers – including some of RDC's largest customers – were purchasing and dispensing large quantities of highly-abused controlled substances, and little

else. In particular, the majority of the purchases made by Pharmacy-1, RDC's largest customer during the relevant period, were for controlled substances, including oxycodone and fentanyl. Pharmacy-1 was RDC's largest Subsys purchaser. Additionally, Pharmacy-1 was a large purchaser of oxycodone; not only did Pharmacy-1 purchase at least twenty percent more oxycodone than any other RDC customer, but the size of those purchases grew at an exponential rate. For instance, between October 2012 and October 2013, Pharmacy-1 went from purchasing approximately 70,000 units of oxycodone per month to over 200,000 units per month. Similar patterns of ordering growth continued into 2016. RDC's compliance department, including the Compliance Officer, flagged Pharmacy-1's ordering as suspicious on multiple occasions, stating, for instance, "We can have all the documentation in the world, but I personally feel this is too high for RDC and I think we should not allow them to exceed 80,000 units a month." Similarly, toward the end of 2013, based on dispensing information provided by the compliance department, Executive-2 told Executive-1 that he was "very concerned with the growth of Subsys at [Pharmacy-1]" and his "gut feeling is the risk is to [sic] great versus the reward" and "that [Pharmacy-1] could potentially become a real problem for RDC." Notwithstanding these concerns, RDC continued to supply Pharmacy-1 with oxycodone and fentanyl until approximately June 2017. RDC's concern about the quantities of controlled substances its customers were ordering was not limited to Pharmacy-1. Rather, for multiple other pharmacies, RDC's compliance department regularly noted to senior management, including Executive-1, Executive-2, and the Compliance Officer, customers that were predominantly buying large quantities of highly-abused controlled substances.

b. Certain RDC customer pharmacies were dispensing quantities of controlled substances that were consistently higher than accepted medical standards. This included, in

particular, prescriptions for thirty-day supplies of 180 or more oxycodone 30-milligram tablets, which are the most commonly diverted and abused form of oxycodone. For example, RDC's compliance department found that two pharmacies located in New York City that shared the same owner were, among other things, distributing high monthly dosages of oxycodone 30-milligram tablets, leading RDC's compliance department to conclude that the pharmacies exhibited "red flags" indicating that they were likely engaged in illicit activity. Indeed, as one of RDC's contracted field auditors told Executive-2, the Compliance Officer, and others, the dispensing at those pharmacies was "very high and the average dispensed is like a stick of dynamite waiting for [the] DEA to light the fuse." RDC's compliance staff made similar observations about dispensing for multiple other pharmacy customers. Nevertheless, RDC continued to supply some of those pharmacies distributing high monthly dosages of oxycodone even after RDC's compliance department identified the "red flag" in the pharmacies' dispensing data.

c. Certain RDC customer pharmacies were accepting cash from a large percentage of patients obtaining highly-abused controlled substances, such as oxycodone and fentanyl. Patients paying in cash for controlled substances is a "red flag" of diversion because cash transactions can be concealed from detection by insurance companies, state regulators, and law enforcement. The DEA and outside auditors repeatedly informed RDC throughout the relevant period that pharmacies that accepted more than ten percent of its payments for controlled substances in cash were exhibiting a "red flag" of diversion of controlled substances. During that same time period, RDC's compliance department identified multiple customers who accepted cash payments that greatly exceeded the ten percent threshold, and RDC continued to distribute controlled substances to those customers. For example, in September 2014, a member of RDC's compliance department determined that a pharmacy customer of RDC in Pittsburgh, Pennsylvania ("Pharmacy-2") was

distributing large quantities of suboxone – an opioid used to treat opioid addiction, which is also frequently abused – and that approximately sixty percent of the suboxone prescriptions filled were paid for in cash. When RDC's compliance department contacted Pharmacy-2, the pharmacy explained that ninety-five percent of its cash-paying customers were from a neighboring state with prescribing limits that caused them to travel across the border, which was itself a "red flag" of diversion. One of RDC's consulting field auditors raised the issue with Executive-1, noting that this was "a DEA investigation in the making," but while Executive-1 agreed that it was not "going to end well," RDC did not cease doing business with Pharmacy-2. Instead, after one of RDC's auditors visited the pharmacy, the clinic that was referring individuals to Pharmacy-2 started "insuring" its cash-paying customers so that the percentage of prescriptions paid for in cash at Pharmacy-2 decreased. But despite such manipulation, RDC did not investigate Pharmacy-2 further and did not terminate Pharmacy-2 as a customer until May 2018, when RDC learned that Pharmacy-2 was under investigation for diversion of controlled substances.

d. RDC's compliance department also identified multiple pharmacy customers that were filling prescriptions for patients who had traveled from great distances – including from different states – to fill prescriptions for controlled substances. The fact that a pharmacy fills prescriptions for patients who have traveled from long distances – and likely passed by pharmacies that are close and more convenient – is a "red flag" of diversion because it indicates that pharmacies local to the patients refused to fill the patients' prescriptions. As was the case with Pharmacy-2, RDC distributed controlled substances to customers that had a significant number of customers traveling from great distances to obtain controlled substances, and continued to distribute to those customers even after RDC's compliance department had identified the "red flag" and reported it to the Compliance Officer and senior management.

e. RDC's compliance department also noted, in reviewing dispensing data, that pharmacy customers were filling prescriptions issued by practitioners who were prescribing controlled substances outside the scope of their medical practice or specialty, on RDC's "watch list," or under DEA investigation. Indeed, RDC supplied multiple pharmacies that filled prescriptions written by physicians who were under DEA investigation and were later prosecuted and convicted for diverting controlled substances, including Dr. Robert Terdiman, Dr. Kevin Lowe, Dr. Rogelio Lucas, Dr. Ernesto Lopez, Dr. Martin Tesher, and Dr. David Taylor, among others. All of these physicians were flagged on RDC's watch list, and yet RDC continued to distribute controlled substances to pharmacies that had filled prescriptions they wrote.

29. The concerns RDC's compliance department expressed about the dispensing of numerous pharmacy customers and the "red flags" of diversion were conveyed to RDC's senior management, including Executive-1. Specifically, the Compliance Officer regularly apprised RDC's senior management of compliance problems with particular pharmacies by email, and also at regular in-person meetings (and later, during the relevant period, on telephone calls) with Executive-1 and Executive-2. Additionally, and taken together, the number of "red flags" associated with RDC customers prompted various employees and managers at RDC to conclude that there were substantial and pervasive compliance issues with RDC's customers. Indeed, in January 2013, RDC's head of sales commented to Executive-1, Executive-2, and the Compliance Officer that "we have some VERY suspicious customers due to their buying" and "[i]f anyone other than [the Compliance Officer] were to look [at] the reports" it would be a "scary story." RDC employees, including Executive-2 and the Compliance Officer, frequently expressed similar sentiments about RDC's customers to Executive-1.

30. Nonetheless, despite the fact that RDC routinely observed "red flags" surrounding the dispensing of multiple customers, the company – at the direction of Executive-1 – largely ignored these warning signs, continued to distribute controlled substances to customers that were illegitimately dispensing these narcotics, and refused to terminate or cut off sales of controlled substances to those customers. Executive-1 made the decisions not to terminate RDC's relationship with customers that RDC's compliance department determined were likely diverting controlled substances. Executive-1 instructed RDC's employees to "educate and work with [its] customers" instead of cutting them off. In fact, and as reflected in an email the Compliance Officer sent to Executive-1, if RDC were to determine that it needed "to stop selling to even one store," the Compliance Officer would "always consult with [Executive-1] first." Consistent with that understanding, the Compliance Officer consulted with Executive-1 on the possible cessation of business with customers. The compliance department was always guided by the directions of senior management and, in particular, Executive-1. In general, the guidance Executive 1 provided was to work with a customer and not terminate the relationship.

31. As a result of RDC's senior management's directives, RDC rarely terminated its relationships with pharmacy customers, and continued to supply customers with controlled substances for months or years after encountering substantial evidence that the drugs those pharmacies dispensed were being used illicitly. For instance, despite the "red flags" identified by RDC's compliance department, RDC did not terminate its relationship with Pharmacy-1, Pharmacy-2, or several other problematic pharmacy customers until at least 2017. That was, in part, because RDC's senior management directed the compliance department to work with RDC's problematic customers – in particular, customers who were shareholders, board members, or owed debts to RDC – and not terminate them. In total, from 2012 through February 2017, RDC only

terminated its relationship with seventeen of its 1,300 pharmacy customers, and in multiple cases, the reason for termination was not compliance related.

32. In almost every case, RDC terminated its relationship with pharmacy customers for compliance reasons only when the customer refused to comply with RDC's requests or when a continued relationship with the customer exposed RDC to immediate legal consequences. For example, in March 2015, if not earlier, RDC's compliance department identified a New York City pharmacy ("Pharmacy-3"), which was one of RDC's largest customers and an RDC shareholder, as a "large concern of RED FLAG diversions [sic]." Those "red flags" identified by the compliance department included dispensing a large amount of oxycodone and Subsys; more than thirty percent of payments in cash; filling prescriptions written by doctors who were under investigation by the DEA; routinely exceeding its controlled substance order thresholds; and filling prescriptions for patients coming from out-of-state. Specifically, in March 2015, following an onsite visit at the pharmacy, one of RDC's compliance auditors noted that Pharmacy-3 was "really bad with prescribers we do not care for." Those concerns continued for months even as RDC continued to distribute controlled substances to Pharmacy-3. For instance, in September 2015, one of the employees in RDC's compliance department noted that Pharmacy-3 "continue[s] to fill for cash and doctors who are suspicious and have been warned against" and concluded that Pharmacy-3 was "a risk . . . and shouldn't be a customer." Another RDC employee around the same time described the dispensing at Pharmacy-3 as "evil," and in October 2015, one of RDC's compliance auditors again noted "the previously communicated concerns of the RDC Compliance Team regarding the pharmacy's filling [] of questionable controlled substances prescriptions written by several physicians." Despite concerns from RDC's compliance personnel about Pharmacy-3, RDC continued supplying the pharmacy until November 2015. Indeed, just weeks

before RDC terminated Pharmacy-3 as a customer, one of RDC's compliance department employees told two other employees, "I can't tell you not to release orders if [the Compliance Officer] tells you to do so, but I wouldn't let them go over their limits. It makes me sick to my stomach to see they purchased so much from us last month." RDC ultimately terminated the pharmacy only after it refused to cooperate with RDC and, among other things, allow RDC to review its dispensing reports.

RDC'S MISREPRESENTATIONS TO THE DEA AND WILLFUL FAILURE TO FILE SUSPICIOUS ORDER REPORTS

RDC's Compliance Policies and Representations to the DEA

33. At the time RDC received the DEA Letters in 2006 and 2007, it had no system in place to identify or report suspicious orders of controlled substances. After receiving the letters, in 2007 or early 2008, Executive-1 instructed the Compliance Officer to develop a program to identify and monitor suspicious orders. The Compliance Officer consulted Executive-1 and Executive-2, along with other members of RDC's senior management, in designing the suspicious order monitoring program and formulating the accompanying suspicious order monitoring guidance. In or about March 2009, RDC completed its system for identifying suspicious orders and reporting those orders to the DEA. In general, RDC's program identified "orders of interest," which were controlled substance orders that exceeded predetermined ordering thresholds set for a customer. If an identified order was "suspicious" because it was of an unusual size, deviated from a customer's normal pattern of ordering, was of an unusual frequency, or was likely to be diverted from legitimate channels, then RDC's compliance department was required, as part of the program, to report the order to the DEA and not ship the order to the customer. In or about June 2009, the DEA visited RDC as part of a regularly-scheduled audit, and at that time, RDC showed the DEA

its computer system for identifying suspicious orders and explained its suspicious order reporting procedure, including that it would report to the DEA all orders that it had identified as suspicious.

34. At the June 2009 audit, and at subsequent visits by, in conversations with, and in letters to the DEA, RDC represented to the DEA that it had a standard operating procedure relating to conducting due diligence on customer orders. For instance, in a March 2012 letter to the DEA, RDC stated that it was using a system to monitor its sales of controlled substances, and as part of its program, "any order that [was] placed and would go over the customer's usage . . . would be stopped" until "proper documentation from [the] customer [was] obtained." Again, in or about July 2013, RDC provided to the DEA a copy of its standard operating procedure for identifying suspicious orders.

35. In September 2014, RDC received a legal opinion from its outside counsel, which was sent to Executive-1 and later shared with Executive-2, regarding RDC's compliance with its legal obligation to identify and report suspicious orders to the DEA. That legal opinion reviewed RDC's legal obligation, pursuant to 21 C.F.R. § 1301.74(b), to report suspicious orders to the DEA, and recommended, among other things, that RDC make changes to its compliance program. In late 2014, RDC's outside counsel was tasked with working with RDC, including the Compliance Officer, to draft a revised standard operating procedure for suspicious order reporting. That revised standard operating procedure for conducting customer due diligence and suspicious order monitoring was finalized in or about January 2015. The 2015 policy provided that "[p]rior to selling controlled substances to any customer, RDC must obtain, review, and verify . . . drug dispensing data," and "will assess whether each prospective . . . customer dispenses controlled substances for legitimate medical purposes." The policy also identified RDC's legal requirement to report suspicious orders, pursuant to 21 C.F.R. § 1301.74(b), and provided that "RDC will

review and monitor every controlled substance order to determine whether they are suspicious orders that cannot be filled and must be reported to DEA." RDC subsequently shared its 2015 policy with the DEA, including in connection with its application for a license to operate a new facility in Fairfield, New Jersey.

36. In November 2016, the DEA conducted an audit of RDC's facility in Rochester, New York. Following that audit, in January and February 2017, RDC's customer due diligence and suspicious order reporting policy were revised. At no time between the revision in January 2015 and January 2017 did RDC make any written change to its customer due diligence and suspicious order reporting policy, or notify the DEA of any change in its due diligence and reporting procedures.

The Consent Decree

37. In or about August 2013, the DEA and the Office initiated an investigation regarding RDC's failure to file with the DEA automated, comprehensive drug reporting system ("ARCOS") reports, which are monthly reports of all sales and shipments of controlled substances by a manufacturer or distributor. On July 8, 2015, RDC entered into a consent order in the Southern District of New York (the "Consent Decree"), in which RDC admitted to CSA violations for failing to properly file ARCOS reports with DEA from 2012 to 2014. RDC paid a $360,000 civil penalty in connection with the Consent Decree, and was required to cure its prior reporting failures by compiling and re-reporting the missing ARCOS data for the DEA. In connection with the negotiations surrounding the Consent Decree, representatives of the DEA and the Office reminded RDC about its obligations under the CSA to, among other things, report suspicious orders to the DEA. Approximately one week after the entry of the Consent Decree, Executive-1

stated in an email to other RDC employees, "I spoke to some stores today about this and they said they completely understand that the DEA is fining everyone and $360 is a low number."

RDC's Opening of Accounts Without Conducting Due Diligence

38. In early 2015, after RDC and its outside counsel finalized the revised 2015 due diligence and suspicious reporting policy – which had been created, at least in part, in response to the investigation that led to the Consent Decree – the Compliance Officer presented the policy to the company's sales team, as well as to Executive-1 and Executive-2. The revised policy represented that RDC would, among other things conduct due diligence on all pharmacies' dispensing practices before onboarding them as customers. Executive-1 and Executive-2 expressed that they did not favor the new policy because of its effect on the company's sales representatives. In March 2015, for example, Executive-1 lamented to Executive-2 and the Compliance Officer, among others, that "there is NO return" on the company's compliance program. Around the same time, Executive-2 echoed that sentiment, telling the Compliance Officer that the new policy was not giving the sales team a "fighting chance" when it came to opening new customer accounts.

39. During the same period, RDC was bringing on new customers that concerned the company's compliance department. Specifically, shortly before the Compliance Officer announced RDC's revised customer due diligence and suspicious order monitoring policy in 2015, he complained to other members of the compliance department in an email that "all the new stores we are bringing on have baggage." That was, according to a compliance department field auditor, at least in part, because "everyone is being cut off by [other distributors] and running over to RDC . . . we are picking up rejects from other distributors." To that, the Compliance Officer responded, "you are making me sick just reading this," and another compliance department employee added

that she found herself "literally cringing when we have new accounts now because of how the dispensing has looked." At the direction of Executive-1, however, the RDC sales team continued to open accounts and begin selling to problematic new customers, some of which had previously had their distribution arrangements with other wholesalers terminated. As a result, RDC's compliance department experienced delays in authorizing the sale of controlled substances to new customers, because compliance department personnel believed it was necessary to scrutinize new customers' dispensing data before making any sales.

40. In or about July 2015, after receiving complaints from sales representatives about the length of time it was taking for RDC's compliance department to approve the opening of new accounts, Executive-1 declared that even though he had "no idea if [a new pharmacy customer] is a good guy or bad guy . . . it is taking too long [to open an account] no matter what the problem is." Executive-1 added in a subsequent email, "I know we have to do due diligence but we have the tail wagging the dog. . . . this HAS to stop. . . . Do the compliance after opening. And close it if it looks funny." That same month, Executive-1, Executive-2, and the Compliance Officer, among others, met to discuss revising RDC's 2015 due diligence and suspicious reporting policy to eliminate the requirement that customer due diligence be conducted before opening an account. After the meeting, RDC made the decision to begin opening accounts without completing due diligence on the pharmacies' dispensing data, and without changing the policy. The Compliance Officer informed Executive-1 and Execcutive-2 that RDC should formalize this change in writing and notify the DEA of its change in practice, given that the company had previously represented to the DEA that it was conducting due diligence of all new accounts. However, RDC neither changed its written procedures concerning account opening nor notified the DEA of its change in policy.

41. RDC began distributing controlled substances to new customers without conducting due diligence on the customers' dispensing practices. In multiple cases, after bringing on new customers without conducting due diligence and supplying them with controlled substances for months, RDC discovered significant problems in the dispensing records for those customers – including high dosage opioid prescriptions and accepting a high percentage of cash from patients – that indicated the pharmacies were unlawfully distributing controlled substances.

42. In or about June 2016, Executive-1 again pushed to accelerate the process for opening new accounts. Specifically, on June 5, 2016, Executive-1 emailed Executive-2, the Compliance Officer, and members of RDC's sales team: "Based on recent government change[s] I want to accelerate our account opening process. As soon as our credit managers completely approve our credit app we will open an account right away. We will continue to do our diligence on controls but not before we open the account." The "recent government changes" were, according to Executive-1, that "the government has recently told the DEA to lay off wholesalers . . . and concentrate on fixing the problem with more addiction programs." Executive-2 stated that he agreed with Executive-1 that "we should open the account and then conduct the due diligence review." The Compliance Officer responded that if management made the change, he "would suggest that [the company's counsel] change our [standard operating procedure] to state that . . . we made a change." The Compliance Officer emphasized that because the existing standard operating procedure "states that RDC will conduct a review prior to opening [a new customer] to controls," RDC's change should "be documented so we may show DEA when they are in the next time for an audit."

43. In late June 2016, the Compliance Officer sought the opinions of two of RDC's compliance field auditors – both of whom had prior law enforcement experience – about

Executive-1's proposal to open new customer accounts without conducting due diligence. Those employees told the Compliance Officer that they did not agree with changing RDC's approach to due diligence, and their opinions were conveyed to Executive-1 and Executive-2. Executive-1 responded in an email: "That is bullshit!" and insisted on speaking to the auditors. In a subsequent meeting between Executive-1, Executive-2, and the auditors, Executive-1 told the auditors that opening accounts without conducting due diligence would be the company's policy going forward in light of the government's change in enforcement priorities. The auditors told Executive-1 that the change was a mistake from a compliance standpoint because RDC had an obligation under the CSA to know its customers and guard against diversion.

44. At the direction of Executive-1, however, RDC continued to open new customer accounts without conducting due diligence on prospective customers' dispensing. RDC did not amend its written policies or notify the DEA of its change in its account opening practices. For multiple customers that had accounts opened without conducting due diligence, compliance employees subsequently determined that those customers displayed "red flags" of diversion of controlled substances to illegitimate channels.

RDC's Failure to File Suspicious Order Reports with the DEA

45. Since at least 2009, RDC has operated a system designed to detect suspicious orders. RDC's automated system was created to identify "orders of interest," which were defined by RDC as controlled substance orders that "exceeded normal purchasing patterns." Normal purchasing patterns were established using monthly threshold "allowable limits" for controlled substances, which were calculated based on a multiple of the pharmacy customer's average purchases of the relevant drug family over the preceding 12 months. Whenever a customer exceeded that "allowable limit" threshold, RDC's system held the order and flagged it as an "order

of interest" for RDC's compliance staff. RDC's compliance staff was then responsible for reviewing the held "order of interest," the pharmacy customer's dispensing data, and any other documentation provided by the pharmacy prior to releasing an order for shipment, in order to determine whether the order was "suspicious." While RDC's policies changed from time to time, they generally provided that an "order of interest" was "suspicious" if it deviated from legitimate business practices or evinced a "red flag" of diversion of controlled substances. The DEA's regulation concerning the reporting of suspicious orders – which was binding on RDC as a registrant – similarly defined suspicious orders as orders of unusual size, deviating substantially from normal practice, or of unusual frequency. Under RDC's policies, suspicious orders could not be filled and, pursuant to the DEA regulation, had to be reported to the DEA.

46. Despite RDC's suspicious order reporting policies – which it conveyed to the DEA – and its regulatory obligations, RDC failed to report suspicious orders to the DEA. Specifically, from 2012 through 2016, RDC received and fulfilled over 1.5 million orders for controlled substances from its pharmacy customers, including hundreds of thousands of orders for frequently-abused drugs, such as oxycodone, fentanyl, and hydrocodone. During this period, RDC only reported four suspicious orders to the DEA, notwithstanding senior management's awareness of the company's reporting obligations under the CSA. RDC failed to report to the DEA at least two thousand orders of controlled substances made by its pharmacy customers that should have been reported as suspicious pursuant to the criteria set forth in 21 C.F.R. § 1301.74(b) and the guidance contained in letters from the DEA.

47. Many of RDC's pharmacy customers – including its largest customers – exhibited ordering patterns that generated "orders of interest" and should have resulted in further investigation to determine whether the pharmacies, and/or certain physicians who prescribed drugs

dispensed by the pharmacies, were engaging in opioid diversion. Specifically, through reports that RDC received reflecting the controlled substances that its pharmacy customers had dispensed, on-site visits of its customers, and other sources, RDC internally identified "red flags" suggesting that certain pharmacy customers may have been dispensing controlled substances that were not for legitimate medical purposes. For example, many of RDC's customers exhibited the following dispensing patterns:

a. A high percentage of the pharmacy's controlled substance sales, and particularly sales of oxycodone 30-milligram tablets, were paid for in cash as opposed to through insurance.

b. An unusually high proportion of the pharmacy's overall dispensing consisted of controlled substances.

c. A disproportionate percentage of the pharmacy's controlled substance purchases were for highly-abused drugs, such as oxycodone 30-milligram tablets or fentanyl patches or spray.

d. The pharmacy filled prescriptions for controlled substances for many patients who lived great distances from the pharmacy.

e. The pharmacy frequently filled prescriptions for quantities or dosages of controlled substances that were higher than accepted medical standards.

f. The pharmacy filled prescriptions for controlled substances written by prescribers on RDC's internal watch list.

48. Notwithstanding these "red flags" – including in the rare instances when RDC determined that a pharmacy should be terminated as a customer – RDC did not file suspicious order reports with the DEA for orders placed by these pharmacy customers. RDC did not report

suspicious orders because Executive-1 directed that RDC should be "the knight in shining armor" for independent pharmacies, and should work with pharmacies instead of reporting them. Consistent with that direction, the Compliance Officer instructed compliance department employees verbally and in writing on multiple occasions that "we do not turn in a store" merely based on suspicions of wrongdoing by the customer, but rather choose "to educate and work with our customers."

49. Not only did RDC ignore dispensing patterns and "red flags" associated with orders that should have prompted the filing of reports with the DEA, but RDC's compliance department – consistent with the directive from Executive-1 and Executive-2 to avoid reporting customers – took steps to prevent reporting of suspicious orders and the future flagging of orders as "orders of interest." For example, while RDC's order of interest system identified approximately 8,300 "orders of interest" from 2012 through 2016, RDC did not comply with its own policies after flagging these orders, and instead filled nearly all these "orders of interest" without taking steps to determine whether there was a legitimate explanation for an increase in a pharmacy customer's order volume. RDC rarely contacted the pharmacy that placed the "order of interest" to obtain the reason for the increased ordering, and regularly failed to obtain updated controlled substance dispensing information from the customer before releasing the order to be shipped. In fact, the compliance department staff was trained to mark flagged orders "not suspicious," falsely note that "dispensing data supports" the increase in controlled substances orders, and release orders to pharmacies without reviewing the pharmacies' current dispensing data. The Compliance Officer, at the direction of Executive-1, also released "orders of interest" in the evening or during the weekend for large customers or pharmacies owned by board members, even after the compliance staff had flagged such orders as "suspicious." For example, in March 2013, when Pharmacy-1

exceeded its order limit for oxycodone, the Compliance Officer wrote to Executive-1 and Executive-2 that while "[t]echnically by our [standard operating procedure] we should make a call and stop selling." The company, nevertheless, continued to supply controlled substances to the customer.

50. Additionally, in order to prevent the generation of future "orders of interest," and therefore avoid triggering the requirement to report a suspicious order to the DEA, the company's compliance department increased the threshold limit of controlled substances a pharmacy could purchase from RDC. Even in the rare instance in which RDC attempted to limit customers' ordering, RDC did not report suspicious orders by those customers, or the customers themselves, to the DEA. RDC knew that such a practice was contrary to law. For example, in 2012, after attending a conference hosted by the DEA, an RDC employee told Executive-1, Executive-2, and the Compliance Officer that the DEA had stated that "if we currently have stores that are constantly hitting our suspicious order report [threshold] . . . we cannot just simply cut them back, on the drug that is causing the alert. . . . by cutting them back, we are telling the account[] [t]hat a little bit of Diversion, is okay." Nonetheless, throughout the relevant time period, RDC manipulated customers' "allowable limit" thresholds but did not report orders.

51. In February 2017, the Civil Division of the Office first served a document request to RDC. In November 2017, the Criminal Division of the Office served a subpoena on RDC. Following receipt of these requests, RDC reported hundreds of suspicious orders to the DEA relating to customers that it has had for years, and has reported at least 400 suspicious order reports in each year since RDC was the subject of an investigation by the Office.

EXHIBIT D

Compliance Addendum

1. RDC shall maintain and implement a Controlled Substance Monitoring Program ("CSMP") that is designed to identify and report suspicious orders and maintain effective controls against the diversion of controlled substances. The CSMP shall meet the requirements set forth in this Compliance Addendum. The CSMP shall apply to all DEA-registered RDC distribution centers.

2. The effective date of the Compliance Addendum shall be the date upon which the Stipulation and Order of Settlement and Dismissal is approved by the Court. The obligations contained in this Compliance Addendum shall remain in full force and effect for a period of three years from the Effective Date, unless otherwise specified herein.

3. RDC acknowledges and agrees that the obligations undertaken in this Compliance Addendum do not fulfill the totality of RDC's obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders of controlled substances pursuant to the Controlled Substances Act, 21 U.SC. §§ 801 *et seq.* ("the CSA"), and applicable regulations promulgated by DEA.

4. Definitions. The below terms shall be defined as follows for purposes of this Compliance Addendum:

a. The term "threshold" means the total monthly volume of a controlled substance as defined under the CSA, or a particular category of controlled substances, that RDC allows a pharmacy customer to purchase in any particular calendar month before triggering the investigation and approval process set forth in Paragraph 5(b) below.

b. The term "highly diverted controlled substances" means the controlled substances that RDC designates as being subject to the most restrictive thresholds and/or

supplemental due diligence because such substances have a higher risk of diversion compared to other controlled substances. RDC's list of highly diverted controlled substances currently includes, and shall continue to include, the following: (i) oxycodone; (ii) hydrocodone; (iii) hydromorphone; (iv) methadone; (v) morphine; (vi) carisoprodol; (vii) alprazolam; (viii) tramadol; (ix) oxymorphone; (x) fentanyl; (xi) amphetamine; and (xii) buprenorphine. RDC shall add other controlled substances to the list of highly diverted controlled substances as needed based on information obtained from DEA and other sources related to drug diversion trends.

c. The term "order" means a unique pharmacy customer request on a specific date for a certain amount of a specific dosage form or strength of a controlled substance in one given instance, regardless of other requests made concurrently with that given request. For the purposes of this definition, each line item on an invoice or DEA Form 222 is a separate order.

d. The term "dispensing activity data" means the following information regarding the controlled substances dispensed by a pharmacy during a specific period: (a) the prescription number; (b) the patient's zip code; (c) the drug's name, strength, dosage form, and National Drug Code ("NDC") number; (d) the quantity of the drug dispensed and the days supply; (e) the date the drug was dispensed; (f) the prescriber's name and DEA number; (g) the method of payment; and (h) the total number of prescriptions dispensed, broken down by controlled and non-controlled substances.

5. Within 90 days of the Effective Date, RDC shall implement improved CSMP procedures and systems to review all orders of controlled substances and to detect and report suspicious orders to DEA.

a. RDC shall review and enhance its methodology for calculating and establishing appropriate thresholds designed to detect potentially suspicious orders from pharmacy customers. These thresholds shall be based not only on the customer's historical dispensing activity data, but also on the ordering patterns of comparable pharmacy customers. RDC shall set more restrictive thresholds for orders of highly diverted controlled substances. RDC shall establish appropriate initial thresholds for new customers prior to supplying them with any controlled substances. RDC compliance personnel shall be exclusively responsible for establishing and modifying initial thresholds, and may consult with other RDC personnel to gather information relevant to such determinations.

b. RDC shall not fulfill any order that exceeds the customer's threshold without conducting a thorough and diligent investigation to determine whether the order is suspicious and must be reported to DEA. This investigation shall include, but not be limited to, contacting the customer to obtain an explanation for the increase in ordering and obtaining and reviewing a report from the customer reflecting its most recent dispensing activity data. RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the order is suspicious and must be reported to DEA. Any decision that an order is not suspicious and need not be reported to DEA must be approved in writing by RDC's Chief Compliance Officer, Director of Compliance, or Assistant Director of Compliance. In addition, RDC will notify the Independent Monitor in writing of any decision that results in fulfilling an order that exceeds a customer's threshold.

c. RDC shall review and enhance its procedures and systems for evaluating and approving customer requests for increased thresholds ("Threshold Change Requests"). Prior

to approving a Threshold Change Request, RDC shall conduct a thorough and diligent investigation to determine whether the increased threshold is warranted. This investigation shall include, but not be limited to, contacting the customer to obtain the basis for the Threshold Change Request, obtaining and reviewing a report from the customer reflecting its most recent dispensing activity data, and conducting an on-site visit to the pharmacy if the pharmacy has not been subject to a site visit within the prior six months. RDC compliance personnel shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the Threshold Change Request should be approved. RDC shall not temporarily increase thresholds in order to circumvent the requirement to conduct Threshold Change Request investigations. Any increase in a customer's thresholds must be approved in writing by RDC's Chief Compliance Officer, Director of Compliance, or Assistant Director of Compliance. In addition, RDC will notify the Independent Monitor in writing of any decision that results in the approval of a customer's Threshold Change Request.

d. RDC shall review and enhance its procedures and systems for detecting patterns or trends in customer orders and dispensing activity that indicate a pharmacy may be dispensing controlled substances for other than a legitimate medical purpose ("Red Flags"). In the event that RDC identifies a Red Flag for a pharmacy customer, RDC shall conduct a thorough and diligent investigation to determine whether any orders or customer Red Flags should be reported to DEA. Red Flags include, but are not limited to:

(i) A high percentage of the pharmacy's controlled substance sales are paid for in cash.

(ii) The pharmacy fills prescriptions for many patients who live far from the pharmacy.

(iii) The pharmacy frequently fills prescriptions for higher quantities than the accepted medical standards.

(iv) A high percentage of the pharmacy's overall dispensing consists of controlled substances.

(v) A disproportionate percentage of the pharmacy's controlled substance sales are for highly diverted controlled substances.

(vi) The pharmacy fills prescriptions written by prescribers acting outside their practice or specialty.

(vii) The pharmacy fills prescriptions for prescribers who have been subject to discipline or a law enforcement action.

(viii) The pharmacy dispenses the same quantity of highly diverted controlled substances to most patients.

(ix) Additional red flags identified by DEA to RDC in writing or otherwise published by DEA.

Upon identification of one or more Red Flags, RDC shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that there is a legitimate explanation for the identified Red Flag(s). RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.

e. RDC shall electronically submit all suspicious orders to DEA Headquarters. DEA agrees to provide RDC with instructions and procedures for electronically submitting suspicious orders. RDC shall submit the suspicious order reports in the format as

defined by DEA pursuant to reporting requirements to the centralized database as defined in the SUPPORT Act, § 3292, or as otherwise designated by DEA. RDC shall also submit all suspicious order reports to the DEA Field Division, and these reports shall specify the basis for reporting the order. RDC shall transmit suspicious order reports, if any, to DEA Headquarters and the DEA Field Division within two business days of discovery. RDC shall not fulfill any order deemed to be suspicious.

6. Within 90 days of the Effective Date of this Stipulation, RDC shall implement improved CSMP procedures and systems for conducting due diligence reviews of pharmacy customers to prevent the diversion of controlled substances.

a. RDC shall review and enhance its customer on-boarding procedures and systems to better assess whether prospective customers dispense controlled substances for only legitimate medical purposes. RDC shall, to the extent possible, verify any information that is self-reported by the prospective customer and relied upon to make this assessment. Prior to initiating the sale of controlled substances to a pharmacy, RDC compliance personnel, or a qualified third party consultant acting on behalf of RDC, shall engage in at least the following due diligence: (i) conduct an on-site visit to the pharmacy and interview the pharmacist-in-charge; (ii) complete a report reflecting the findings based on this visit and interview and noting any areas of concern; (iii) review recent dispensing activity data for the pharmacy to identify any Red Flags; (iv) determine whether the pharmacy or the pharmacist-in-charge has been subject to any disciplinary action, and, if so, the basis for the disciplinary action; and (v) conduct a diligent inquiry to determine whether another distributor has previously suspended the pharmacy's ability to purchase controlled substances, and, if so, the reason. In the event that RDC identifies a Red Flag that does not have a legitimate explanation or RDC's due diligence reveals any other

credible information suggesting that the pharmacy may be engaging in diversion, RDC shall not sell controlled substances to the pharmacy and shall report its findings and the results of its due diligence review to the DEA Field Division within two business days.

b. RDC shall review and enhance its procedures and systems for conducting meaningful due diligence of existing customers that purchase controlled substances to better assess whether existing customers dispense controlled substances for only legitimate medical purposes. RDC compliance personnel, or a qualified third party consultant acting on behalf of RDC, must engage in at least the following due diligence for each controlled substance customer: (i) conduct on-site visits and interviews of the pharmacist-in-charge, which shall be done at least once a year for RDC's 100 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least once every three years for all other controlled substances customers; (ii) complete a report reflecting their findings based on the visit and interview and noting any areas of concern; (iii) at least three times each calendar year for RDC's 100 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least two times each calendar year for all other controlled substances customers, obtain and review the pharmacy's dispensing activity data for the prior three months to identify any Red Flags; (iv) obtain updated completed questionnaires from the pharmacy on an annual basis; and (v) conduct all necessary additional due diligence in response to any information or events raising concerns of potential diversion activities (*e.g.*, the receipt of reliable information from law enforcement about possible diversion, the receipt of information regarding the suspension or revocation of a DEA registration or state license). . Upon identification of any credible information suggesting that an existing customer may be

engaging in diversion, including the presence of one or more Red Flags, RDC shall report its findings and the results of its due diligence review to the DEA Field Division within two business days. In addition, upon identification of such evidence suggesting diversion, including the presence of one or more Red Flags, RDC shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that no such diversion is occurring, including that there is a legitimate explanation for the evidence suggesting diversion and the identified Red Flag(s). RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.

c. All steps taken with respect to the due diligence review of prospective or existing customers shall be documented in the customer's file.

7. RDC shall ensure that all policies and procedures relating to its CSMP are included in an updated version of its compliance manual ("CSMP Manual").

8. RDC shall submit periodic reports to DEA Headquarters, the United States Attorney's Office for the Southern District of New York (the "SDNY"), and the Independent Monitor. RDC shall submit its first report within 90 days of the Effective Date. After making its first report, RDC shall thereafter make a report every 180 days (a "Reporting Period"). The reports shall be submitted on or before the last day of each Reporting Period. Each report shall include the following:

a. A list of all RDC compliance personnel, as well as any third-party consultants used by RDC to perform compliance functions.

b. RDC's list of highly diverted controlled substances as of the end of the Reporting Period.

c. A list of RDC's 20 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the Reporting Period, and a breakdown of the sales of highly diverted controlled substances to each of these customers during the Reporting Period.

d. A description of the methodology used during the Reporting Period to calculate and establish thresholds for new and existing RDC pharmacy customers, as well as any changes that were made to the methodology since the prior Reporting Period.

e. The total number of suspicious orders reported to DEA during the Reporting Period.

f. A copy of any version of the CSMP Manual that was in effect during the Reporting Period, which shall include, among other things, a description of the manner in which RDC identified and reported suspicious orders to DEA during the Reporting Period and a description of the procedures and systems in place during the Reporting Period to conduct due diligence reviews of new and existing pharmacy customers.

9. RDC agrees that DEA personnel may enter its registered locations at any time during regular business hours, without prior notice, to verify compliance with this Compliance Addendum. RDC will permit entry of DEA personnel without an Administrative Inspection Warrant. RDC personnel shall sign a Notice of Inspection when requested to do so by DEA personnel during regular business hours.

10. RDC shall maintain customer due diligence files and all other records sufficient to document compliance with this Compliance Addendum during the period from the Effective Date through six months after the last Reporting Period.

11. RDC may notify the Independent Compliance Monitor of any material provision set forth in this Compliance Addendum that it believes is unduly burdensome, inconsistent with applicable law or regulation, excessively expensive, or otherwise inadvisable, as well as the basis for such conclusion. Such notification shall be sent to the Monitor and the Office, and must include a written proposal of an alternative approach, policy, procedure or system that RDC believes will achieve the same objective or purpose as the challenged provision. The Office shall in its sole discretion, determine whether to accept RDC's proposed revision, to maintain the existing provision, or to adopt a different alternative.

EXHIBIT E

Independent Compliance Monitor Mandate

1. **Monitorship, Duration.** Rochester Drug Co-operative Inc. ("RDC") agrees to retain an independent compliance monitor (the "Monitor") for three years from the date of appointment of the Monitor.

2. **Selection of Candidates, Timing.** RDC agrees to retain a Monitor upon selection by the Office of the United States Attorney for the Southern District of New York (the "Office") whose powers, rights, and responsibilities are set forth herein. Within ten (10) calendar days of the Effective Date of the Agreement, RDC shall provide to the Office a list of three (3) qualified candidates to serve as the Monitor. RDC may identify its preference for the Monitor and provide a basis for such preference. Within thirty (30) calendar days of receiving the final list of qualified Monitor candidates from RDC, the Office shall select and notify RDC in writing of its selection of the Monitor. The Office shall consult with RDC, using its best efforts to select and appoint a mutually acceptable Monitor (and any replacement Monitors, if required) as promptly as possible. Within thirty (30) calendar days of receiving written notice of the selection of the Monitor, RDC shall retain the Monitor and finalize all terms of engagement, supplying a copy of an engagement letter to the Office. In the event that the Office is unable to select a Monitor acceptable to RDC, the Office shall have the sole right to select a monitor (and any replacement Monitors), if required. To ensure the integrity of the Monitorship, the Monitor must be independent and objective, and the following persons shall not be eligible as either a Monitor or an agent, consultant or employee of the Monitor: (a) any person currently or previously employed by RDC; any current or former RDC board member; any person who holds an interest in RDC, or has a relationship with RDC, its affiliates, related entities, or its employees, officers or directors; or (b) any person who has been directly adverse to RDC in any proceeding. In addition, RDC must certify in writing that it will not employ or be affiliated with the Monitor for a period of not less than one year from the date

that the Monitorship is terminated. The parties shall endeavor to complete the monitor selection process within 60 days of the execution of the RDC Deferred Prosecution Agreement (the "Agreement"). The selection of the Monitor must be approved by the Deputy Attorney General.

3. **Mandate.** The Monitor shall take steps, as described herein, to provide reasonable assurance that RDC establishes and maintains compliance systems, controls and processes reasonably designed, implemented and operated to ensure RDC's compliance with the terms of the Agreement, including the Compliance Addendum in Exhibit ___, as well as reducing the risk of any recurrence of RDC's misconduct as described in the Information and Statement of Facts (the "Mandate"). To fulfill the Mandate, the Monitor shall, among other things: (i) evaluate the effectiveness of RDC's processes, procedures and programs to ensure compliance with the diversion and reporting requirements of the CSA; (ii) make recommendations to such processes, procedures and programs to reasonably ensure such compliance; (iii) assess whether RDC complies with the diversion and reporting requirements of the CSA and the policies and procedures relating to its Controlled Substance Monitoring Program, or CSMP; (iv) assess the qualifications of employees added to the RDC compliance department after the Effective Date of the Agreement; (v) assess RDC's Board of Directors' and senior management's commitment to, and effective implementation of, CSA compliance procedures; and (vi) make periodic reports concerning the foregoing. The Monitor shall have the authority to take such reasonable steps as, in his or her view, may be necessary to fulfill the Mandate.

4. **Monitor's Work Plan.** The Monitor shall prepare a written work plan (the "Work Plan") within sixty (60) calendar days of being retained. In the Work Plan, the Monitor shall recommend those tasks and efforts that it believes are necessary to fulfill the Mandate, and identify with reasonable specificity the activities the Monitor plans to undertake in execution of the

Mandate. In creating the Work Plan, the Monitor may develop an understanding of the facts and circumstances surrounding any violations that may have occurred before the date of the Agreement, but shall rely on available information and documents provided by RDC, and not conduct his or her own inquiry into such violations. The Monitor shall submit the Work Plan to RDC and the Office, which shall in turn provide comments, if any, within fourteen (14) calendar days after receipt of the Work Plan. Any disputes between RDC and the Monitor with respect to the Work Plan shall be decided by the Office in its sole discretion.

5. **Progress Reports.** Following approval of the Work Plan, the Monitor shall undertake to ensure that RDC adopts and implements the recommendations set forth in the Work Plan. The Monitor's efforts shall commence no later than ninety (90) calendar days from the date of the engagement of the Monitor (unless otherwise agreed by RDC, the Monitor, and the Office). Thereafter, the Monitor shall issue reports ("Progress Reports") no less frequently than every one-hundred and twenty days following approval of the Work Plan until issuance of the Final Report (see paragraph seven). Such Progress Reports shall include (i) a narrative summary of the Monitor's progress to date in achieving the Mandate; (ii) an updated Work Plan, to include the status, projected completion dates and other relevant information concerning the adoption of the Monitor's preexisting recommendations, as well as of any new recommendations the Monitor believes are necessary to fulfill the Mandate; and (iii) any issues, obstacles or difficulties that may prevent the Monitor from achieving the Mandate. The Monitor shall provide the finished report to the Board of Directors of RDC and contemporaneously transmit copies to the Office.

6. **Dispute Resolution:** Within sixty (60) calendar days after receiving a Progress Report, RDC shall adopt and implement the recommendations in the Progress Report unless, within fourteen (14) calendar days of receiving the Progress Report, RDC notifies in writing the

Monitor and the Office of any recommendations that RDC considers unduly burdensome, inconsistent with applicable law or regulation, impractical, excessively expensive, or otherwise inadvisable. With respect to any such recommendation, RDC need not adopt that recommendation within the sixty (60) calendar days of receiving the report but shall propose in writing to the Monitor and the Office an alternative policy, procedure or system designed to achieve the same objective or purpose. In the event RDC and the Monitor are unable to agree on an acceptable alternative proposal, the Office shall in its sole discretion, determine what measures RDC shall undertake, and may consider the Monitor's recommendation and RDC's reasons for not adopting the recommendation in determining whether RDC has fully complied with its obligations under the Agreement. Pending such determination, RDC shall not be required to implement any contested recommendation(s). With respect to any recommendation that the Monitor determines cannot reasonably be implemented within sixty calendar days after receiving the report, the Monitor may extend the time period for implementation with prior written approval of the Office.

7. **Final Report.** Upon the termination of the Monitorship in accordance with paragraph one, the Monitor shall issue a final report (the "Final Report") summarizing the tasks performed under the Work Plan and the results achieved. The Final Report shall also include a narrative summary of the Monitor's overall efforts, discuss any outstanding tasks, and provide future recommendations designed to ensure that RDC remains CSA-compliant after the expiration of the Monitorship. The Monitor shall provide the Final Report to the Board of Directors of RDC and contemporaneously transmit copies to the Office. Any objections to the Final Report shall follow the procedures identified in paragraph six herein.

8. **RDC's Obligations.** RDC shall cooperate fully with the Monitor. To that end, RDC shall facilitate the Monitor's access to RDC's documents, resources, and employees, and not

limit such access, except as provided in paragraph nine. RDC shall provide the Monitor with access to all information, documents, records, facilities, and employees, as reasonably requested by the Monitor, and shall use its best efforts to provide the Monitor with access to RDC's former employees and its third-party vendors, agents, and consultants.

9. **Withholding Access.** The parties agree that no attorney-client relationship shall be formed between RDC and the Monitor. In the event that RDC seeks to withhold from the Monitor access to information, documents, records, facilities, or current or former employees of RDC that may be subject to a claim of attorney-client privilege or to the attorney work-product doctrine, or other recognized privileges and protections, or where RDC reasonably believes production would otherwise be inconsistent with applicable law, RDC shall work cooperatively with the Monitor to resolve the matter to the satisfaction of the Monitor. If the matter cannot be resolved, at the request of the Monitor, RDC shall promptly provide written notice to the Monitor and the Office. Such notice shall include a general description of the nature of the information, documents, records, facilities or current or former employees that are being withheld, as well as the legal basis for withholding access. The Office may then consider whether to make a further request for access to such information, documents, records, facilities, or employees.

10. **Reporting Obligations.** Any disclosure by RDC to the Monitor relating to the CSA, its implementation regulations, or the Agreement shall not relieve RDC of any otherwise applicable obligation to truthfully disclose such matters to the Office or DEA, pursuant to the Agreement and its addendums, or RDC's obligations under the CSA.

11. **Monitor's Discovery of Misconduct.** Should the Monitor discover during the course of his or her engagement that RDC, or any of its officers, employees, directors, consultants, vendors, or customers may have committed a violation of the CSA, or of any federal or state law,

the Monitor shall immediately report such potential misconduct to the Office, unless the misconduct was already disclosed to an appropriate law enforcement body.

12. **Confidentiality**. The Monitor and his or her staff shall maintain the confidentiality of any non-public information entrusted or made available to the Monitor. The Monitor shall share such information only with the Office and the DEA.

13. **Information Designation.** RDC shall clearly identify any portions of any submissions it makes to the Office or DEA pursuant to the Compliance Addendum and the Independent Compliance Monitor Mandate (including the Monitor's Work Plan, Progress Reports, and Final Report) that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, or otherwise potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. RDC shall also be afforded the opportunity to identify any portions of submissions made by the Monitor to the Office or DEA that RDC believes are trade secrets, or information that is commercial or financial and privileged or confidential, or otherwise exempt from disclosure under FOIA. All such information may be exempt from disclosure under FOIA and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release any information identified as confidential by RDC, the Office and DEA agree to provide RDC reasonable opportunity to respond to any such requests.

14. **Non-Disclosure.** The Monitor shall sign a non-disclosure agreement with RDC prohibiting disclosure of information received from RDC to anyone other than to the Office, the DEA, or anyone hired by the Monitor. Within thirty days after the end of the Monitor's term, the Monitor shall either return anything obtained from RDC, or certify that such information has been destroyed. Anyone hired by the Monitor shall also sign a nondisclosure

agreement with similar return or destruction requirements as set forth in this subparagraph.

15. **Hiring Authority**. The Monitor shall have the authority to employ legal counsel, consultants, investigators, experts, and any other personnel necessary to assist in the proper discharge of the Monitor's duties.

16. **Compensation and Expenses**. Although the Monitor shall operate under the supervision of the Office, the compensation and expenses of the Monitor, and of the persons hired under his or her authority, shall be paid by RDC. The Monitor, and any person hired by the Monitor, shall be compensated in accordance with their respective typical hourly rates. RDC shall pay bills for compensation and expenses promptly, and in any event within 30 days. In addition, within one week after the selection of the Monitor, RDC shall make available office space, telephone and internet service, and clerical assistance sufficient for the Monitor to carry out his or her duties.

17. **Indemnification**. RDC shall provide an appropriate indemnification agreement to the Monitor with respect to any claims arising out of the performance of the Monitor's duties.

EXHIBIT F

MEMORANDUM OF AGREEMENT

This Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, the Drug Enforcement Administration ("DEA" or "Government") and Rochester Drug Co-operative, Inc. ("RDC") (each a "Party" and collectively the "Parties"). For purposes of this agreement, RDC shall mean RDC, any of its subsidiaries, affiliates, predecessors, successors, parent companies, and any assigns, officers, directors, employees, and agents of each.

1. RDC, located at 50 Jetview Drive, Rochester, New York, and 116 Lehigh Drive, Fairfield, New Jersey, is a wholesale distributor of pharmaceutical products, including controlled substances. RDC services approximately 1,000 pharmacy customers in 10 states.

2. RDC is registered with DEA, with an expiration date of April 30, 2019, for both of its locations, as a distributor of Schedules II through V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq. ("the CSA" or "Act").

3. In 2016, the New York Division of DEA began investigating RDC's compliance with its obligation to prevent diversion and to report suspicious orders. Specifically, DEA registrants are required to maintain "effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). RDC was also obligated to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and to "inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

4. In lieu of DEA initiating administrative proceedings in this matter, and in the interest of ensuring compliance with the laws and regulations regarding the distribution of controlled substances, the Parties agree to the below terms and conditions.

5. The Parties agree that the facts set forth in the Statement of Facts attached as Exhibit C to the Deferred Prosecution Agreement between RDC and the Office of the United States Attorney for the Southern District of New York ("DPA"), and incorporated herein, are true and accurate.

6. In consideration of RDC's entry into the DPA, and all of the requirements contained therein, during the period of deferred prosecution, the DEA agrees not to suspend, revoke, or initiate proceedings to suspend or revoke RDC's registrations to distribute controlled substances, based on the conduct described in the Statement of Facts described in Paragraph 5 (the "Covered Conduct").

7. Should the DEA in its sole discretion determine that RDC has: (a) knowingly given false, incomplete or misleading information either during the term of the DPA or in connection with DEA's investigation of the Covered Conduct, (b) committed any crime under the federal laws of the United States subsequent to the execution of this Agreement, (c) committed any violation of DEA regulations that would otherwise be a basis for suspending or revoking RDC's registration, or (d) otherwise violated any provision of the DPA, nothing in the DPA or in this Agreement shall preclude the DEA from suspending, revoking or initiating proceedings to suspend or revoke RDC's registration, including based on the Covered Conduct.

8. DEA represents that other than as reflected in Exhibit G to the DPA, it has not referred and agrees to not refer RDC for civil penalty proceedings, based on the Covered Conduct, to any other agency within the Department of Justice.

9. RDC fully and finally releases the United States of America, its employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which it has asserted, could have asserted, or may assert in the future against the United States, its employees, servants, and agents, related to the Covered Conduct and DEA's investigation thereof.

10. Nothing in this Agreement shall prohibit any agency within the Department of Justice, other than DEA, any State or Local entity, or any law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating, or continuing with, administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action or proceeding involving the Covered Conduct. If RDC requests, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming RDC is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed.

11. The terms of this Agreement will not establish any precedent for similar terms being required in any other matter.

12. RDC represents that it has had an opportunity to seek the advice of counsel prior to entering into this Agreement, and that it has knowledge of the events described herein. RDC further represents that it voluntarily enters into this Agreement in order to avoid litigation, without any degree of duress or compulsion.

13. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute the same agreement.

14. The individual(s) signing this Agreement on behalf of RDC represent and warrant that they are authorized by RDC to execute this Agreement. The individual(s) signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

15. This Agreement shall become effective (i.e. final and binding) on the date of signing by the last signatory (the "Effective Date").

16. This Agreement shall remain in effect for five (5) years from the Effective Date unless the parties agree in writing before then to modify or terminate the Agreement.

For Rochester Drug Co-operative, Inc.:

John T. Kinney

NAME John T. Kinney
TITLE INTERIM CEO

4/18/19
Date

For The Drug Enforcement Administration:

John Martin
Assistant Administrator
Diversion Control Division

4/18/19
Date

EXHIBIT G

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. ROCHESTER DRUG CO-OPERATIVE, INC., Defendant.	19 Civ. 3568 (___)

STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL

WHEREAS, on or about April 23, 2019, the United States of America (the "United States" or "Government"), by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York, commenced the above-captioned civil law enforcement action by filing a complaint (the "Complaint") in this Court against Rochester Drug Co-operative, Inc. ("RDC" or "Defendant," and together with the Government, the "Parties");

WHEREAS, this Stipulation and Order of Settlement and Dismissal (this "Stipulation") is entered into among the United States and RDC by their authorized representatives;

WHEREAS, RDC is a regional wholesale drug cooperative that distributes drugs, including controlled substances, and healthcare products to approximately 1,300 independently-owned pharmacies in several states;

WHEREAS, RDC is a DEA-registered distributor of Schedule II through V controlled substances under the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* ("the CSA");

WHEREAS, RDC operates distribution centers in Rochester, New York and Fairfield, New Jersey;

WHEREAS, on or about July 6, 2015, RDC entered into a Consent Order with the United States to resolve a prior investigation into RDC's failure to comply with its reporting obligations under the CSA, including RDC's failure to electronically report to the DEA acquisition/distribution transactions of controlled substances through the DEA's Automation of Reports and Consolidated Orders System ("ARCOS") and RDC's failure to include controlled substances theft and loss data in its ARCOS reports;

WHEREAS, the regulations promulgated under the CSA require distributors of controlled substances to design and operate a system to detect "suspicious orders" for controlled substances, and to inform the DEA of such orders when discovered, *see* 21 C.F.R. § 1301.74(b);

WHEREAS, suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," *see id.*;

WHEREAS, on or about September 27, 2006 and December 27, 2007, the DEA sent letters to all DEA-registered distributors of controlled substances, including RDC, that discussed the requirements of 21 C.F.R. § 1301.74(b) and contained guidance for the identification and reporting of suspicious orders to the DEA (the "DEA Letters");

WHEREAS, the DEA's suspicious order reporting requirements for controlled substances are an integral part of its efforts to identify and prevent the illicit distribution of narcotics and other dangerous drugs;

WHEREAS, the CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. § 1301.74(b), *see* 21 U.S.C. § 842(a)(5); 21 U.S.C. § 842(c);[1]

WHEREAS, the Complaint alleges that between May 2012 and November 2016 (the "Covered Period"), RDC repeatedly violated 21 C.F.R. § 1301.74(b) by knowingly failing to operate an adequate system to detect, investigate, and report to the DEA suspicious orders of controlled substances, including thousands of suspicious orders of oxycodone, fentanyl, hydrocodone, amphetamine, and buprenorphine products (the "Covered Conduct");

WHEREAS, in connection with settlement discussions, RDC has submitted information concerning its financial condition to the United States, including but not limited to information relating to RDC's assets, liabilities, lines of credit, revenues, profits, and financial projections ("Financial Information");

WHEREAS, the Parties have reached a mutually agreeable resolution of the claims against RDC in the Complaint;

WHEREAS, on or about the date it entered into this Stipulation, RDC also entered into a Deferred Prosecution Agreement (the "DPA") with the Criminal Division of the United States Attorney's Office for the Southern District of New York in connection with a three-count Information charging RDC with, among other things, knowingly failing to furnish suspicious order reports to the DEA in violation of 21 U.S.C. §§ 842(a)(5) and (c)(2);

NOW, THERFORE, upon the Parties' agreement IT IS HEREBY ORDERED:

[1] The maximum penalty for a violation increased to $15,040 for penalties assessed after January 29, 2018, where the associated violation occurred after November 2, 2015. *See* 28 C.F.R. § 85.5.

TERMS AND CONDITIONS

1. The Court's subject matter jurisdiction is undisputed and RDC consents to the Court's exercise of personal jurisdiction over it.

2. RDC admits, acknowledges, and accepts responsibility for the following conduct during the Covered Period:

a. RDC knowingly failed to implement an adequate system to detect, investigate, and report suspicious orders of controlled substances to the DEA. RDC received and fulfilled over 1.5 million orders for controlled substances from its pharmacy customers, including hundreds of thousands of orders for highly-abused drugs, such as oxycodone, fentanyl, and hydrocodone. However, during this period, RDC reported only a total of 4 suspicious orders to the DEA, notwithstanding senior management's awareness of the company's reporting obligations under the CSA. RDC failed to report to the DEA at least two thousand orders of controlled substances made by its pharmacy customers that should have been reported as suspicious pursuant to the criteria set forth in 21 C.F.R. § 1301.74(b) and the guidance contained in the DEA Letters.

b. Several of RDC's largest pharmacy customers exhibited ordering patterns that should have resulted in further investigation to determine whether the pharmacies, and/or certain physicians who prescribed drugs dispensed by the pharmacies, were engaging in opioid diversion. RDC frequently failed to conduct such further investigation. Several physicians who wrote a large number of prescriptions filled by RDC customers were subsequently arrested and prosecuted for diversion. RDC failed to maintain effective controls to prevent such diversion and failed to report frequent unexplained sharp spikes in opioid orders.

c. Through reports that RDC received reflecting the controlled substances that its pharmacy customers had dispensed, on-site visits of its customers, and other sources, RDC internally identified "red flags" suggesting that certain pharmacy customers were dispensing controlled substances that were not for legitimate medical purposes. For example, several of RDC's largest pharmacy customers exhibited the following dispensing patterns:

i. A high percentage of the pharmacy's controlled substance sales, and particularly sales of oxycodone 30-milligram tablets, were paid for in cash as opposed to through insurance. Oxycodone 30-milligram tablets are the most commonly abused form of oxycodone.

ii. An unusually high proportion of the pharmacy's overall dispensing consisted of controlled substances.

iii. A disproportionate percentage of the pharmacy's controlled substance purchases were for highly-abused drugs, such as oxycodone 30-milligram tablets or fentanyl patches or spray.

iv. The pharmacy filled prescriptions for controlled substances for many patients who lived great distances from the pharmacy.

v. The pharmacy frequently filled prescriptions for quantities or dosages of controlled substances that were higher than accepted medical standards.

Notwithstanding these "red flags," RDC did not file suspicious order reports with the DEA for orders placed by these pharmacy customers.

d. RDC maintained an internal list that identified prescribers who had been arrested, investigated by state or federal government agencies, subject to state administrative proceedings, or whom RDC compliance personnel had identified as engaging in suspicious prescribing activities ("Suspicious Prescriber List"). Several of RDC's largest pharmacy customers filled large numbers of prescriptions written by prescribers on the Suspicious Prescriber List, and RDC continued to sell controlled substances to these pharmacies well after placing the prescribers on the list.

e. RDC developed and implemented a system to identify "orders of interest." The system automatically generated an alert each time a pharmacy customer's order for a drug in a particular category of controlled substances exceeded a monthly purchase threshold that RDC had set for drugs in that category. The monthly thresholds were calculated based on a multiple of the pharmacy customer's average purchases of the relevant drugs over the preceding 12 months. Accordingly, for a customer's drug purchases to exceed the monthly threshold, there would need to have been a significant spike in the customer's ordering of the relevant drugs during that month. RDC's system identified approximately 7,800 "orders of interest" from January 2013 through the end of the Covered Period. RDC filled nearly all these "orders of interest," frequently without taking reasonable steps to determine whether there was a legitimate explanation for the significant spike in the pharmacy customer's order volume. RDC rarely contacted the pharmacy that placed the "order of interest" to obtain the reason for the increased ordering, and regularly failed to obtain recent controlled substance dispensing information from the customer before releasing the order to be shipped. RDC did not report any of the approximately 7,800 "orders of interest" to the DEA. Instead, to prevent the generation of future "orders of interest," RDC often raised the purchase thresholds for certain high-volume customers so that these customers could continue to increase their opioid purchases and dispensing over time.

f. RDC failed to implement an adequate due diligence program to prevent the diversion of controlled substances by its pharmacy customers. RDC failed to devote sufficient resources to its compliance program and employed compliance personnel who lacked necessary qualifications and relevant experience when they were hired. RDC compliance personnel and contractors did not conduct field visits for most of its pharmacy customers, and

failed to consistently obtain and review updated and complete dispensing reports that would have allowed it to better detect troubling dispensing patterns. In addition, RDC frequently began selling controlled substances to new pharmacy customers without conducting an adequate review of the pharmacy's operations, background, and historical dispensing patterns. RDC's sales staff were involved in screening and approving new customers despite the fact that they received payments for each new customer enrolled.

g. RDC's top customer during the Covered Period was a specialty pharmacy located in Woodbury, New York. This pharmacy was one of the largest providers of Subsys, a highly-addictive fentanyl spray that is approved by the FDA only for use by cancer patients with breakthrough pain. This pharmacy was also a large provider of oxycodone; between October 2012 and October 2013, the pharmacy went from purchasing approximately 70,000 units of oxycodone per month to purchasing over 200,000 units per month. This pharmacy filled a high volume of prescriptions written by prescribers included on RDC's Suspicious Prescriber List, including numerous physicians who were subsequently arrested for diversion.

3. RDC shall pay to the United States a civil penalty of $20,000,000 (the "Settlement Amount"). RDC may satisfy its obligation to pay the Settlement Amount by complying with its obligations under Paragraphs 3-6 of the DPA, including but not limited to consenting to the forfeiture of $20,000,000 and paying this amount to the United States in accordance with the schedule set forth in the DPA.

4. RDC shall be in default if it fails to pay the Settlement Amount as set forth in Paragraph 3 ("Default"). The Government shall provide written notice to RDC of any Default in the manner set forth in Paragraph 28 below. RDC shall then have an opportunity to cure the Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default ("Uncured Default"), interest shall accrue at the rate specified in Paragraph 6 of the DPA on the remaining unpaid principal balance of the Settlement Amount. In the event of an Uncured Default, RDC shall agree to entry of a consent judgment in favor of the United States against RDC in the amount of the Settlement Amount as attached hereto as Exhibit A; in the event that RDC has paid a portion of the Settlement Amount prior to the Uncured Default, RDC

may, within ten (10) business days of the Uncured Default, execute and deliver to the United States a substitute consent judgment that includes only the amount of the unpaid portion of the Settlement Amount. The United States may also, at its option, (a) rescind this Stipulation and reinstate the claims asserted against RDC in the Complaint; (b) seek compliance with this Stipulation; (c) offset the remaining unpaid balance of the Settlement Amount from any amounts due and owing RDC by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. RDC shall not contest any offset imposed or any collection undertaken by the Government pursuant to this Paragraph, either administratively or in any federal or state court. In addition, RDC shall pay the Government all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, RDC shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Covered Conduct.

5. RDC shall promptly report to the DEA all suspicious orders as defined in the CSA and its implementing regulations, including but not limited to 21 C.F.R. § 1301.74. RDC shall promptly report to the DEA any of its customers that it knows or has reason to believe are distributing controlled substances outside the scope of professional practice and not for a legitimate medical purpose.

6. RDC shall voluntarily submit to DEA inspections conducted pursuant to 21 C.F.R. § 1316.03 at any time without condition and without advance notice.

7. RDC shall maintain and implement a Controlled Substances Monitoring Program that meets the requirements set forth in the Compliance Addendum attached as Exhibit B to this Stipulation. All of the terms sets forth in the Compliance Addendum are incorporated herein and shall be deemed part of this Stipulation. As set forth in the DPA, RDC shall retain an independent compliance monitor (the "Monitor") who, among other things, will be responsible for assessing and monitoring compliance with the Compliance Addendum. The manner in which the Monitor will be selected, the Monitor's responsibilities and mandate, and the Monitor's reporting obligations are set forth in Exhibit E to the DPA.

8. Defendant agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation, including but not limited to any investigation of current or former RDC employees or any pharmacy that purchased controlled substances from RDC. Upon reasonable notice, Defendant shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Defendant further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

9. Subject to the exceptions in Paragraphs 11 and 15 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon Defendant's full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, the United States releases Defendant from any civil claim for

penalties that the United States has for the Covered Conduct under 21 U.S.C. § 842. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Defendant from liability of any kind.

10. Defendant fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Defendant has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, or agents related to the Covered Conduct and the United States' investigation, prosecution and settlement thereof.

11. Notwithstanding the releases given in Paragraph 9 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:

a. any liability arising under Title 26, United States Code (Internal Revenue Code);

b. any criminal liability;

c. any administrative claims and liability, including but not limited to any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 and 824, for mandatory or permissive exclusion from federal healthcare programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) or 42 U.S.C. § 1320a-7b (permissive exclusion), and for suspension or debarment from participating in transactions with federal agencies;

d. any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. any liability based upon obligations created by this Stipulation; and

f. any liability of individuals.

12. RDC has provided Financial Information to the United States and the United States has relied on the accuracy and completeness of that Financial Information in reaching this Stipulation. RDC warrants that the Financial Information is complete, truthful, and accurate. If the United States learns of any misrepresentation in the Financial Information, or of assets in which RDC had an interest at the time of this Stipulation that were not disclosed in the Financial Information, and if such nondisclosure or misrepresentation changes the stated net income set forth in the Financial Information by $500,000 or more or the value of the stated assets set forth in the Financial Information by 5% or more, the United States may at its option: (i) rescind this Stipulation and reinstate the claims asserted against RDC in the Complaint, or (ii) let the Stipulation stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net income or assets that were previously not disclosed. RDC agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorneys' fees and expenses.

13. RDC waives and shall not assert any defenses RDC may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Stipulation bars a remedy sought in such criminal prosecution or administrative action.

14. RDC, having truthfully admitted to the facts set forth in Paragraph 2, agrees that it shall not, through its attorneys, agents, or employees, make any statement, in litigation or otherwise, contradicting the facts set forth in Paragraph 2 or its representations in this Stipulation. Consistent with this provision, RDC may raise defenses and/or assert affirmative claims and defenses in any proceedings brought by private and/or public parties as long as doing so does not contradict the facts set forth in Paragraph 2 or such representations. Any such contradictory statement by RDC or its present or future attorneys, agents, or employees shall constitute a violation of this Stipulation. The decision as to whether any such contradictory statement will be imputed to RDC for the purpose of determining whether RDC has violated this Stipulation shall be within the sole discretion of the Office of the United States Attorney for the Southern District of New York (the "Office"). Upon the Office's notifying RDC of any such contradictory statement, RDC may avoid a finding of violation of this Agreement by repudiating such statement both to the recipient of such statement and to the Office within four business days after having been provided notice by the Office. RDC consents to the public release by the Office, in its sole discretion, of any such repudiation. Nothing in this Stipulation is meant to affect the obligation of RDC or its officers, directors, agents or employees to testify truthfully to the best of their personal knowledge and belief in any proceeding. Nothing in this paragraph applies to statements made, in litigation or otherwise, by any present or former officers, directors, agents or employees of RDC that are made solely in an individual capacity, and not on behalf of RDC.

15. RDC represents and warrants that it has reviewed its financial situation, that it currently is not insolvent as such term is defined in 11 U.S.C. § 101(32), and that it reasonably believes that it shall remain solvent following payment to the Government of the Settlement

Amount. Further, the Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to RDC, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which RDC was or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).

16. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, RDC commences any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors or a third party commences any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of RDC's debts, or seeking to adjudicate RDC as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for RDC or for all or part of RDC's assets, RDC agrees as follows:

a. RDC's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and RDC shall not argue or otherwise take the position in any such case, action, or proceeding that (i) RDC's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) RDC was insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a

contemporaneous exchange for new value given to RDC.

b. If any of RDC's obligations under this Stipulation are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its option, may rescind the release in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against RDC for the claims that would otherwise be covered by the release in Paragraph 9 above. RDC agrees that (i) any such claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the case, action, or proceeding described in the first sentence of this Paragraph, and RDC shall not argue or otherwise contend that the Government's claim, action, or proceeding is subject to an automatic stay; (ii) RDC shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to RDC that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date; and (iii) the Government has a valid claim against RDC in the amount of the Settlement Amount and the Government may pursue its claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding.

c. RDC acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.

17. Defendant agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Office of Management and Budget ("OMB") Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards published at 2 C.F.R. §§ 200 *et seq.*; the Department of Health and Human Services adoption of the OMB Guidance provided at 45 C.F.R. § 75, subpart E *et seq.*; the Federal Acquisition Regulation, 48 C.F.R. §§ 31.205-47 where applicable; or otherwise as specified by federal statutes, regulations or the terms and conditions of a federal award) incurred by or on behalf of Defendant, including its present or former officers, directors, employees, and agents in connection with:

(1) the matters covered by this Stipulation;

(2) the United States' audit(s) and civil or criminal investigation(s) of matters covered by this Stipulation;

(3) Defendant's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil or criminal investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);

(4) the negotiation and performance of this Stipulation; and

(5) any payment Defendant makes to the United States pursuant to this Stipulation, including expenses, costs and attorneys' fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal

Employees Health Benefits Program (FEHBP) (hereinafter referred to as "Unallowable Costs").

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Defendant, and Defendant shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Defendant shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs (as defined in this Paragraph) included in payments previously sought by Defendant from the United States. Defendant agrees that the United States, at a minimum, shall be entitled to recoup from Defendant any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. Any payments due shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States, including the Department of Justice and/or the affected agencies, reserves its right to audit, examine, or re-examine Defendant's books and records and to disagree with any calculation submitted by Defendant or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Defendant, or the effect of any such Unallowable Costs on the amounts of such payments.

d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

18. This Stipulation is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity except as otherwise provided herein.

19. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation.

20. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.

21. This Stipulation is governed by the laws of the United States.

22. The Court shall retain jurisdiction over the enforcement and interpretation of this Stipulation and all disputes that arise thereunder.

23. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

24. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. No prior agreements, oral representations or statements shall be considered part of this Stipulation. This Stipulation may not be amended except by written consent of the Parties. Any amendment to the Compliance Addendum agreed to in writing by the Parties shall not require Court approval.

25. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and the entities indicated below.

26. This Stipulation is binding on RDC and RDC's successors, transferees, and assigns.

27. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

28. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

Jeffrey K. Powell
Jacob M. Bergman
Assistant United States Attorneys
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2706/2776
Email: Jeffrey.Powell@usdoj.gov
Jacob.Bergman@usdoj.gov

TO DEFENDANT RDC:

Douglas B. Farquhar, Esq.
Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, D.C. 20005
Telephone: (202) 737-9624
Email: DFarquhar@hpm.com

29. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the "Effective Date").

Dated: Apr 12, 2019

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York
Attorney for Plaintiff United States of America

By: _____
JEFFREY K. POWELL
JACOB M. BERGMAN
Assistant United States Attorneys
86 Chambers Street
New York, New York 10007
Telephone: (212) 637-2706/2776
Email: Jeffrey.Powell@usdoj.gov
Jacob.Bergman@usdoj.gov

ROCHESTER DRUG CO-OPERATIVE, INC.

By: _____
JOHN KINNEY
Interim Chief Executive Officer

HYMAN, PHELPS, & MCNAMARA, P.C.
Attorneys for ROCHESTER DRUG CO-OPERATIVE, INC.

By: _____

DOUGLAS B. FARQUHAR, ESQ.
Hyman, Phelps & McNamara, PC
700 13th Street, NW, Suite 1200
Washington, D.C. 20005
Telephone: (202) 737-9624
Email: DFarquhar@hpm.com

SO ORDERED:

_____, 2019

_____
HONORABLE _____, U.S.D.J.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

19 Civ. 3568 (___)

ROCHESTER DRUG CO-OPERATIVE, INC.,

Defendant.

CONSENT JUDGMENT

Upon the consent of Plaintiff the United States of America and Defendant Rochester Drug Co-operative, Inc. ("Defendant,"), it is hereby

ORDERED, ADJUDGED and DECREED: that plaintiff the United States of America is awarded judgment in the amount of $20,000,000 as against Defendant, as well as post-judgment interest at the rate of 12% per annum compounded daily.

Agreed to by:

Dated: April 23, 2019

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York
Attorney for Plaintiff United States of America

By:

JEFFREY K. POWELL
JACOB M. BERGMAN
Assistant United States Attorneys
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Jacob.Berman@usdoj.gov

ROCHESTER DRUG COOPERATIVE, INC.

By: John T. Kinney

JOHN KINNEY
Interim Chief Executive Officer

HYMAN, PHELPS, & MCNAMARA, PC
Attorneys for ROCHESTER DRUG COOPERTAIVE, INC.

By: _____

DOUGLAS B. FARQUHAR, ESQ.
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Washington, D.C. 20005
Telephone: (212) 841-0681
Telephone: 202-737-9624
Email: DFarquhar@hpm.com

SO ORDERED:

_____, 2019

HONORABLE _____, U.S.D.J.

Compliance Addendum

1. RDC shall maintain and implement a Controlled Substance Monitoring Program ("CSMP") that is designed to identify and report suspicious orders and maintain effective controls against the diversion of controlled substances. The CSMP shall meet the requirements set forth in this Compliance Addendum. The CSMP shall apply to all DEA-registered RDC distribution centers.

2. The effective date of the Compliance Addendum shall be the date upon which the Stipulation and Order of Settlement and Dismissal is approved by the Court. The obligations contained in this Compliance Addendum shall remain in full force and effect for a period of three years from the Effective Date, unless otherwise specified herein.

3. RDC acknowledges and agrees that the obligations undertaken in this Compliance Addendum do not fulfill the totality of RDC's obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders of controlled substances pursuant to the Controlled Substances Act, 21 U.SC. §§ 801 *et seq.* ("the CSA"), and applicable regulations promulgated by DEA.

4. Definitions. The below terms shall be defined as follows for purposes of this Compliance Addendum:

a. The term "threshold" means the total monthly volume of a controlled substance as defined under the CSA, or a particular category of controlled substances, that RDC allows a pharmacy customer to purchase in any particular calendar month before triggering the investigation and approval process set forth in Paragraph 5(b) below.

b. The term "highly diverted controlled substances" means the controlled substances that RDC designates as being subject to the most restrictive thresholds and/or

supplemental due diligence because such substances have a higher risk of diversion compared to other controlled substances. RDC's list of highly diverted controlled substances currently includes, and shall continue to include, the following: (i) oxycodone; (ii) hydrocodone; (iii) hydromorphone; (iv) methadone; (v) morphine; (vi) carisoprodol; (vii) alprazolam; (viii) tramadol; (ix) oxymorphone; (x) fentanyl; (xi) amphetamine; and (xii) buprenorphine. RDC shall add other controlled substances to the list of highly diverted controlled substances as needed based on information obtained from DEA and other sources related to drug diversion trends.

c. The term "order" means a unique pharmacy customer request on a specific date for a certain amount of a specific dosage form or strength of a controlled substance in one given instance, regardless of other requests made concurrently with that given request. For the purposes of this definition, each line item on an invoice or DEA Form 222 is a separate order.

d. The term "dispensing activity data" means the following information regarding the controlled substances dispensed by a pharmacy during a specific period: (a) the prescription number; (b) the patient's zip code; (c) the drug's name, strength, dosage form, and National Drug Code ("NDC") number; (d) the quantity of the drug dispensed and the days supply; (e) the date the drug was dispensed; (f) the prescriber's name and DEA number; (g) the method of payment; and (h) the total number of prescriptions dispensed, broken down by controlled and non-controlled substances.

5. Within 90 days of the Effective Date, RDC shall implement improved CSMP procedures and systems to review all orders of controlled substances and to detect and report suspicious orders to DEA.

a. RDC shall review and enhance its methodology for calculating and establishing appropriate thresholds designed to detect potentially suspicious orders from pharmacy customers. These thresholds shall be based not only on the customer's historical dispensing activity data, but also on the ordering patterns of comparable pharmacy customers. RDC shall set more restrictive thresholds for orders of highly diverted controlled substances. RDC shall establish appropriate initial thresholds for new customers prior to supplying them with any controlled substances. RDC compliance personnel shall be exclusively responsible for establishing and modifying initial thresholds, and may consult with other RDC personnel to gather information relevant to such determinations.

b. RDC shall not fulfill any order that exceeds the customer's threshold without conducting a thorough and diligent investigation to determine whether the order is suspicious and must be reported to DEA. This investigation shall include, but not be limited to, contacting the customer to obtain an explanation for the increase in ordering and obtaining and reviewing a report from the customer reflecting its most recent dispensing activity data. RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the order is suspicious and must be reported to DEA. Any decision that an order is not suspicious and need not be reported to DEA must be approved in writing by RDC's Chief Compliance Officer, Director of Compliance, or Assistant Director of Compliance. In addition, RDC will notify the Independent Monitor in writing of any decision that results in fulfilling an order that exceeds a customer's threshold.

c. RDC shall review and enhance its procedures and systems for evaluating and approving customer requests for increased thresholds ("Threshold Change Requests"). Prior

to approving a Threshold Change Request, RDC shall conduct a thorough and diligent investigation to determine whether the increased threshold is warranted. This investigation shall include, but not be limited to, contacting the customer to obtain the basis for the Threshold Change Request, obtaining and reviewing a report from the customer reflecting its most recent dispensing activity data, and conducting an on-site visit to the pharmacy if the pharmacy has not been subject to a site visit within the prior six months. RDC compliance personnel shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the Threshold Change Request should be approved. RDC shall not temporarily increase thresholds in order to circumvent the requirement to conduct Threshold Change Request investigations. Any increase in a customer's thresholds must be approved in writing by RDC's Chief Compliance Officer, Director of Compliance, or Assistant Director of Compliance. In addition, RDC will notify the Independent Monitor in writing of any decision that results in the approval of a customer's Threshold Change Request.

d. RDC shall review and enhance its procedures and systems for detecting patterns or trends in customer orders and dispensing activity that indicate a pharmacy may be dispensing controlled substances for other than a legitimate medical purpose ("Red Flags"). In the event that RDC identifies a Red Flag for a pharmacy customer, RDC shall conduct a thorough and diligent investigation to determine whether any orders or customer Red Flags should be reported to DEA. Red Flags include, but are not limited to:

(i) A high percentage of the pharmacy's controlled substance sales are paid for in cash.

(ii) The pharmacy fills prescriptions for many patients who live far from the pharmacy.

(iii) The pharmacy frequently fills prescriptions for higher quantities than the accepted medical standards.

(iv) A high percentage of the pharmacy's overall dispensing consists of controlled substances.

(v) A disproportionate percentage of the pharmacy's controlled substance sales are for highly diverted controlled substances.

(vi) The pharmacy fills prescriptions written by prescribers acting outside their practice or specialty.

(vii) The pharmacy fills prescriptions for prescribers who have been subject to discipline or a law enforcement action.

(viii) The pharmacy dispenses the same quantity of highly diverted controlled substances to most patients.

(ix) Additional red flags identified by DEA to RDC in writing or otherwise published by DEA.

Upon identification of one or more Red Flags, RDC shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that there is a legitimate explanation for the identified Red Flag(s). RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.

e. RDC shall electronically submit all suspicious orders to DEA Headquarters. DEA agrees to provide RDC with instructions and procedures for electronically submitting suspicious orders. RDC shall submit the suspicious order reports in the format as

defined by DEA pursuant to reporting requirements to the centralized database as defined in the SUPPORT Act, § 3292, or as otherwise designated by DEA. RDC shall also submit all suspicious order reports to the DEA Field Division, and these reports shall specify the basis for reporting the order. RDC shall transmit suspicious order reports, if any, to DEA Headquarters and the DEA Field Division within two business days of discovery. RDC shall not fulfill any order deemed to be suspicious.

6. Within 90 days of the Effective Date of this Stipulation, RDC shall implement improved CSMP procedures and systems for conducting due diligence reviews of pharmacy customers to prevent the diversion of controlled substances.

a. RDC shall review and enhance its customer on-boarding procedures and systems to better assess whether prospective customers dispense controlled substances for only legitimate medical purposes. RDC shall, to the extent possible, verify any information that is self-reported by the prospective customer and relied upon to make this assessment. Prior to initiating the sale of controlled substances to a pharmacy, RDC compliance personnel, or a qualified third party consultant acting on behalf of RDC, shall engage in at least the following due diligence: (i) conduct an on-site visit to the pharmacy and interview the pharmacist-in-charge; (ii) complete a report reflecting the findings based on this visit and interview and noting any areas of concern; (iii) review recent dispensing activity data for the pharmacy to identify any Red Flags; (iv) determine whether the pharmacy or the pharmacist-in-charge has been subject to any disciplinary action, and, if so, the basis for the disciplinary action; and (v) conduct a diligent inquiry to determine whether another distributor has previously suspended the pharmacy's ability to purchase controlled substances, and, if so, the reason. In the event that RDC identifies a Red Flag that does not have a legitimate explanation or RDC's due diligence reveals any other

credible information suggesting that the pharmacy may be engaging in diversion, RDC shall not sell controlled substances to the pharmacy and shall report its findings and the results of its due diligence review to the DEA Field Division within two business days.

b. RDC shall review and enhance its procedures and systems for conducting meaningful due diligence of existing customers that purchase controlled substances to better assess whether existing customers dispense controlled substances for only legitimate medical purposes. RDC compliance personnel, or a qualified third party consultant acting on behalf of RDC, must engage in at least the following due diligence for each controlled substance customer: (i) conduct on-site visits and interviews of the pharmacist-in-charge, which shall be done at least once a year for RDC's 100 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least once every three years for all other controlled substances customers; (ii) complete a report reflecting their findings based on the visit and interview and noting any areas of concern; (iii) at least three times each calendar year for RDC's 100 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least two times each calendar year for all other controlled substances customers, obtain and review the pharmacy's dispensing activity data for the prior three months to identify any Red Flags; (iv) obtain updated completed questionnaires from the pharmacy on an annual basis; and (v) conduct all necessary additional due diligence in response to any information or events raising concerns of potential diversion activities (*e.g.*, the receipt of reliable information from law enforcement about possible diversion, the receipt of information regarding the suspension or revocation of a DEA registration or state license). . Upon identification of any credible information suggesting that an existing customer may be

engaging in diversion, including the presence of one or more Red Flags, RDC shall report its findings and the results of its due diligence review to the DEA Field Division within two business days. In addition, upon identification of such evidence suggesting diversion, including the presence of one or more Red Flags, RDC shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that no such diversion is occurring, including that there is a legitimate explanation for the evidence suggesting diversion and the identified Red Flag(s). RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.

c. All steps taken with respect to the due diligence review of prospective or existing customers shall be documented in the customer's file.

7. RDC shall ensure that all policies and procedures relating to its CSMP are included in an updated version of its compliance manual ("CSMP Manual").

8. RDC shall submit periodic reports to DEA Headquarters, the United States Attorney's Office for the Southern District of New York (the "SDNY"), and the Independent Monitor. RDC shall submit its first report within 90 days of the Effective Date. After making its first report, RDC shall thereafter make a report every 180 days (a "Reporting Period"). The reports shall be submitted on or before the last day of each Reporting Period. Each report shall include the following:

a. A list of all RDC compliance personnel, as well as any third-party consultants used by RDC to perform compliance functions.

b. RDC's list of highly diverted controlled substances as of the end of the Reporting Period.

c. A list of RDC's 20 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the Reporting Period, and a breakdown of the sales of highly diverted controlled substances to each of these customers during the Reporting Period.

d. A description of the methodology used during the Reporting Period to calculate and establish thresholds for new and existing RDC pharmacy customers, as well as any changes that were made to the methodology since the prior Reporting Period.

e. The total number of suspicious orders reported to DEA during the Reporting Period.

f. A copy of any version of the CSMP Manual that was in effect during the Reporting Period, which shall include, among other things, a description of the manner in which RDC identified and reported suspicious orders to DEA during the Reporting Period and a description of the procedures and systems in place during the Reporting Period to conduct due diligence reviews of new and existing pharmacy customers.

9. RDC agrees that DEA personnel may enter its registered locations at any time during regular business hours, without prior notice, to verify compliance with this Compliance Addendum. RDC will permit entry of DEA personnel without an Administrative Inspection Warrant. RDC personnel shall sign a Notice of Inspection when requested to do so by DEA personnel during regular business hours.

10. RDC shall maintain customer due diligence files and all other records sufficient to document compliance with this Compliance Addendum during the period from the Effective Date through six months after the last Reporting Period.

11. RDC may notify the Independent Compliance Monitor of any material provision set forth in this Compliance Addendum that it believes is unduly burdensome, inconsistent with applicable law or regulation, excessively expensive, or otherwise inadvisable, as well as the basis for such conclusion. Such notification shall be sent to the Monitor and the Office, and must include a written proposal of an alternative approach, policy, procedure or system that RDC believes will achieve the same objective or purpose as the challenged provision. The Office shall in its sole discretion, determine whether to accept RDC's proposed revision, to maintain the existing provision, or to adopt a different alternative.